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Intravenous bolus-infusion versus sliding scale of insulin for intra-operative glycemic control in elective laparotomy surgeries

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Abstract: Background: The aim of this study was to assess the bolus-infusion to the sliding scale of insulin approaches, regarding percentage of the operative time with the target capillary blood glucose (CBG) range, total insulin units given to the patients, development of hypoglycemia, and the peri-operative changes in serum potassium (s.k) in elective laparotomy surgeries. Sixty patients, American Society of Anesthesiologists (ASA) physical status II, were randomly divided to either the bolus-insulin infusion (BII) group, or the sliding scale of insulin (SSI) group.

Results: The intra-operative target CBG range was achieved in both groups, with no statistically significant difference between them. However, in the post anesthesia care unit (PACU), the number of patients who achieved the target CBG range was significantly more in the BII group. The decrease in the CBG was statistically significant in the SSI group than in the BII group; starting from 30 minutes after the initial intra-venous (IV) insulin injected, to 240 minutes intra-operatively and in the PACU. No patient in either groups developed hypoglycemia. The mean intra-operative time needed to achieve the target CBG range was statistically significant less in the SSI group. The mean percentage of the operative time with the target CBG range was statistically non-significant higher in the SSI group. The mean total insulin units given were statistically non-significant higher in the SSI group. The peri-operative changes in s.k were statistically non-significant between the two groups.

Conclusions: The BII approach slowly achieved the target CBG range intra-operatively and maintained this target in the PACU, with mean 54.6 ± 28.9% operative time with the target CBG range, and with less mean total insulin units needed than the SSI approach.

Keywords: Bolus insulin infusion, Sliding scale insulin, Intra-operative glycemic control, Peri-operative serum potassium

Background

Perioperative hyperglycemia (Fasting blood glucose FBG ˃ 140 mg/dL) is common in surgical patients (Charity et al., 2015). It was considered as an adaptive stress response and the clinical end point of; increased counter regulatory hormones, decreased glucose uptake, with increased glycogenolysis and gluconeogenesis (McCowen et al., 2001), immune suppression, activation of pro-inflammatory cytokines, use of dextrose containing IV fluids, enteral and parenteral nutrition (Charity et al., 2015), and insulin resistance (Saberi et al., 2008). Diabetic patients have greater incidence of complications; cardiac dysrhythmias, post-operative infection, acute renal failure, ileus, stroke, myocardial ischemia (Godoy et al., 2012), with longer hospital stay, and increased mortality rate (Bhamidipati et al., 2011). Peri-operative glycemic control improves these outcomes (Duggan et al., 2017).

Surgical stress response is variable throughout the operation. Rapidly acting insulin for glycemic control could be given subcutaneously (SC) or IV; which could be done by the bolus infusion or the sliding scale approaches

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(Abdelmalak et al., 2013). SC insulin injection is not preferred in surgeries more than 4 hours duration, due to wide variations in the cutaneous circulation and insulin absorption; due to hypothermia, peripheral vasoconstriction, with intra-operative fluid shifts (Shannon and Leta, 2020; Duggan et al., 2017). The SSI is commonly used to manage peri-operative hyperglycemia. It involves administration of insulin units according to certain CBG range. When used as a sole therapy; it results in under-insulinization and hyperglycemia (Queale et al., 1997; Qureshi, 2012). BII is a dynamic approach; allowing adjustments for changes in insulin sensitivity (Alberti and Thomas, 1979; Umpierrez et al., 2012). IV insulin regimens were confirmed by the ADVANCE trial (Anushka et al., 2008) and the ACCORD study (Hertzel et al., 2008), then by the AAGBI guidelines (Barker et al., 2015).

The aim of the current study was to assess the efficacy of the BII to the SSI approaches; in terms of percentage of the operative time with the target CBG range (140–180 mg/dl). The NICE-SUGAR and Glu Control trials concluded that; this CBG target has lower mortality than the restrictive (tight) CBG target of 81–108 mg/dL, which has 4–6 fold increase in the incidence of hypoglycemia (Finfer et al., 2009; Preiser et al., 2009). In 2018, Abdelmalak found no improvement in surgical outcomes with the restrictive CBG target.

Methods

After obtaining Faculty of Medicine, Ain-Shams University ethical committee approval (FMASU R16/2021), informed consent was taken from 60 patients, ASA physical status II, aged 21–65 years, known to have type 2 diabetes mellitus, with pre-operative FBG $<$ 350 mg/dl, scheduled to undergo elective laparotomy surgeries; expected to exceed 2 hours duration in this randomized study at Ain-Shams University Hospitals. Randomization was done using computer-generated random number tables with sealed opaque envelopes.

Pre-operative history taking, physical examination were done and investigations included; complete blood count, the coagulation profile, liver and kidney function tests, FBG, s.k, glycosylated hemoglobin (HbA_1c) and electrocardiography (ECG). During the pre-anesthetic visit, patients were counseled to continue their non-insulin injectables and oral hypoglycemic drugs (insulin secretagogues, metformin, thiazolidinediones and dipeptidyl peptidase − 4 "DPP-4"), and to stop the sodium glucose co-transporter-2 (SGLT-2) inhibitors the day before surgery (Salpeter, 2010; Joshi et al., 2010; Umpierrez et al., 2013; Handelsman et al., 2016). Patients treated with insulin were counseled to; reduce their basal insulin (glargine or detemir) dose by 25% the evening before or the morning of surgery, if twice daily dosing. Neutral protamine Hagedorn (NPH) insulin and premixed formulations to be reduced; by 20% the evening before surgery and by 50% the morning of surgery (Likavec et al., 2006; Rosenblatt et al., 2012).

For all patients, the CBG was measured pre-operative in the ward every 2 hours by glucometer, (Accu-Chek Performa and Accu-Chek Performa glucose strips; error of measurement is ±15% of the measured glucose values when compared with standard laboratory values), with shifting to sliding scale using rapid acting SC insulin injection at least every 4 hours if the CBG > 140 mg/dl. If CBG > 400 mg/dl; continuous rapid acting insulin infusion was started, with ruling out diabetic ketoacidosis and hyperglycemic hyperosmolar Syndrome (Stephen, 2016).

Exclusion criteria

Patients' refusal, patients taking steroids, patients with active infection, diabetic ketoacidosis, hyperglycemic hyperosmolar syndrome, s. K $<$ 3.5 mEq/L, HbA_1c > 8.5% (Raju et al., 2009), patient's baseline CBG measured in the induction room (0 time) $<$ 180 mg/dl, and the presence of acetone in urine for CBG $>$ 300 mg/dl in the induction room (Fig. 1).

In the induction room, patients had a 20G IV cannula inserted for IV insulin injection and insulin or normal saline (NS) infusion.

Preparation of the study drugs

The rapid acting insulin used was Monocomponent Human Insulin, biosynthetic r-DNA origin-Human Actrapid®(manufactured by the Egyptian Drug trading Company, under license from Novo Nordisk Production SAS. Chartres, France).

In a 1 ml (100 units) insulin syringe, ten international units (IU) (0.1 ml) of rapid acting insulin were added to 0.9 ml NS (1 IU insulin/ 0.1 ml).

In a 10 ml syringe, the calculated insulin units for each patient were taken from the prepared inulin syringe, and then NS was added to have a 10 ml volume.

In a 50 ml syringe installed in an infusion pump, 50 IU (0.5 ml) of rapid acting insulin were added to 49.5 ml of NS (1 IU of insulin/ 1 ml).

Another 50 ml syringe installed in an infusion pump, containing NS only was prepared.

Patients were then divided into 2 equal groups of 30 patients each

Group (BII): Bolus-Infusion approach of rapidly acting crystalline insulin. The patient's baseline CBG (0 min) was divided by 100 (Elizabeth et al., 2017). The calculated insulin units were given from the prepared 10 ml syringe IV over 10 minutes (1 ml/min). Then, the

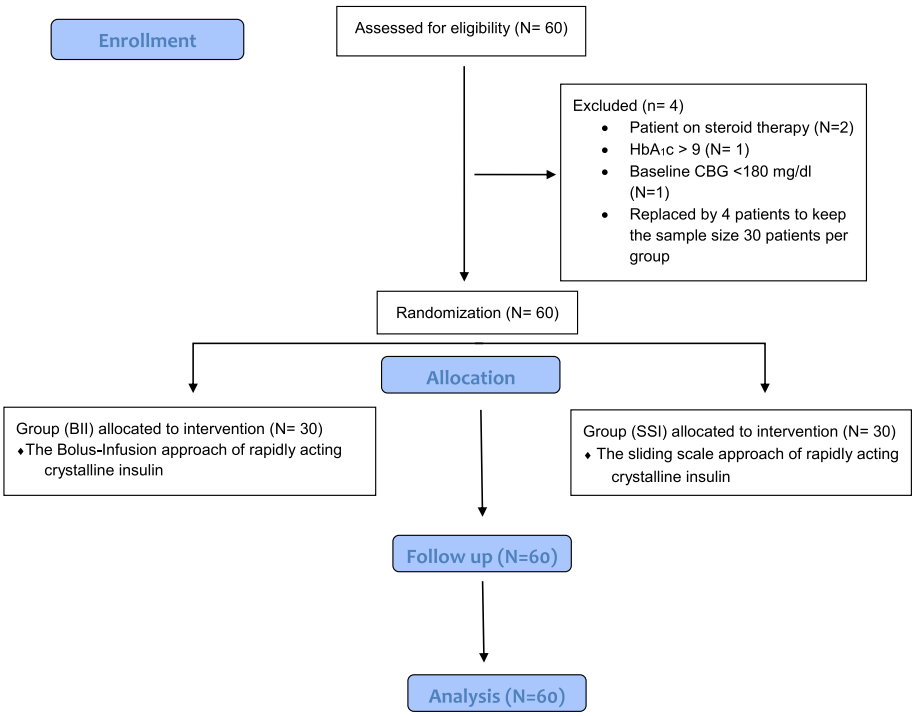

Fig. 1 Flow chart for patients' enrollment and allocation

calculated insulin units were given as an IV infusion/hour (Duggan et al., 2017) by the 50 ml syringe prepared in the syringe pump. The CBG was measured every 30 minutes and in the PACU, and the insulin infusion rate was adjusted by dividing the measured CBG by 100. The insulin infusion was stopped when the CBG was ˂180 mg/dl. Supplemental IV insulin bolus and infusion; was given if the CBG re- increased ≥180 mg/dl after a period of intra-operative glycemic control, and stoppage of the insulin infusion.

Control group (SSI): The sliding scale approach of rapidly acting crystalline insulin was used according to the patient's CBG value; 4 IU of insulin were given for CBG range (180–250 mg/dl), 6 IU of insulin were given for CBG range (251–300 mg/dl), 8 IU of insulin were given for CBG range (301–350 mg/dl) and 10 IU of insulin were given for CBG range (351–400 mg/dl) (Duggan et al., 2017). The required insulin units were given from the prepared 10 ml syringe IV over 10 minutes (1 ml/min). The patient's baseline CBG (0 min) was then divided by 100, and the calculated value was IV infused/hour, by the 50 ml syringe prepared in the syringe pump containing NS only. The CBG was measured every 30 minutes and in the PACU. The NS infusion rate was adjusted according to the measured CBG divided by 100. The NS infusion was stopped when the CBG was ˂180 mg/dl.

If hypoglycemia (CBG < 100 mg/dl) occurred, 10–20 g of hypertonic dextrose (10%) were IV given. CBG measurement was repeated after 15 min with additional dextrose given to maintain the CBG > 100 mg/dl.

The anesthetic technique

On arrival to the operating room, pulse oximetry and non-invasive blood pressure (NIBP) were applied to the patients. An 18 G IV line was secured. Under complete aseptic conditions and local skin infiltration, thoracic epidural catheter was inserted at T_{10-11} or T_{11-12} intervertebral space. Patients were co-loaded with IV 10 ml/kg Ringer's solution. Patients were positioned supine after epidural catheter fixation. Five leads ECG monitor was applied. The epidural was activated by 5 ml of 0.25% bupivacaine after checking the blood pressure of the patient. Maintenance of the epidural analgesia was done with 5 ml/hr. of 0.25% bupivacaine, readjusted according to the patient's hemodynamics.

Induction of general anesthesia and endo-tracheal intubation was done. Central venous line, arterial canulation, and a urinary catheter were secured according to the type of operation. Patients were mechanically ventilated and capnography was attached to the breathing circuit. After completion of surgery and tracheal extubation, patients were transferred to the PACU.

Primary outcome

Efficacy of the BII approach, in terms of percentage of the operative time with the target CBG range (140–180 mg/dl).

Secondary outcomes

1. Extra insulin units given to the patients in both groups: Defined as the sum of the insulin units given all over the operation, after the initial insulin units given.
2. Supplemental IV insulin units given to the patients in the BII approach: Defined as the insulin bolus and infusion units given, for re-increase of the CBG ≥ 180 mg/dl, after a period of intra-operative control in the target CBG range and stoppage of the insulin infusion.
3. Total insulin IU given to the patients in both groups.
4. Number of patients who developed hypoglycemia.
5. Peri-operative changes in serum potassium; measured in the PACU and compared to the baseline pre-operative laboratory level.

Statistical analysis

Sample size calculation was done by the G power program, setting alpha error at 0.05 and power at 80%, assuming a statistically significant difference with large effect size (d˃0.6) between the 2 interventions. Based on these data, a sample size of at least 26 patients per group was needed.

Data were analyzed using Statistical Package for Social Science (SPSS) version 21.0. Chicago, Illinois, USA. Quantitative data were expressed as mean ± standard deviation. Qualitative data were expressed as count. The independent-samples t-test was used to compare between means in the 2 groups. Chi square test was used to compare proportions between two qualitative

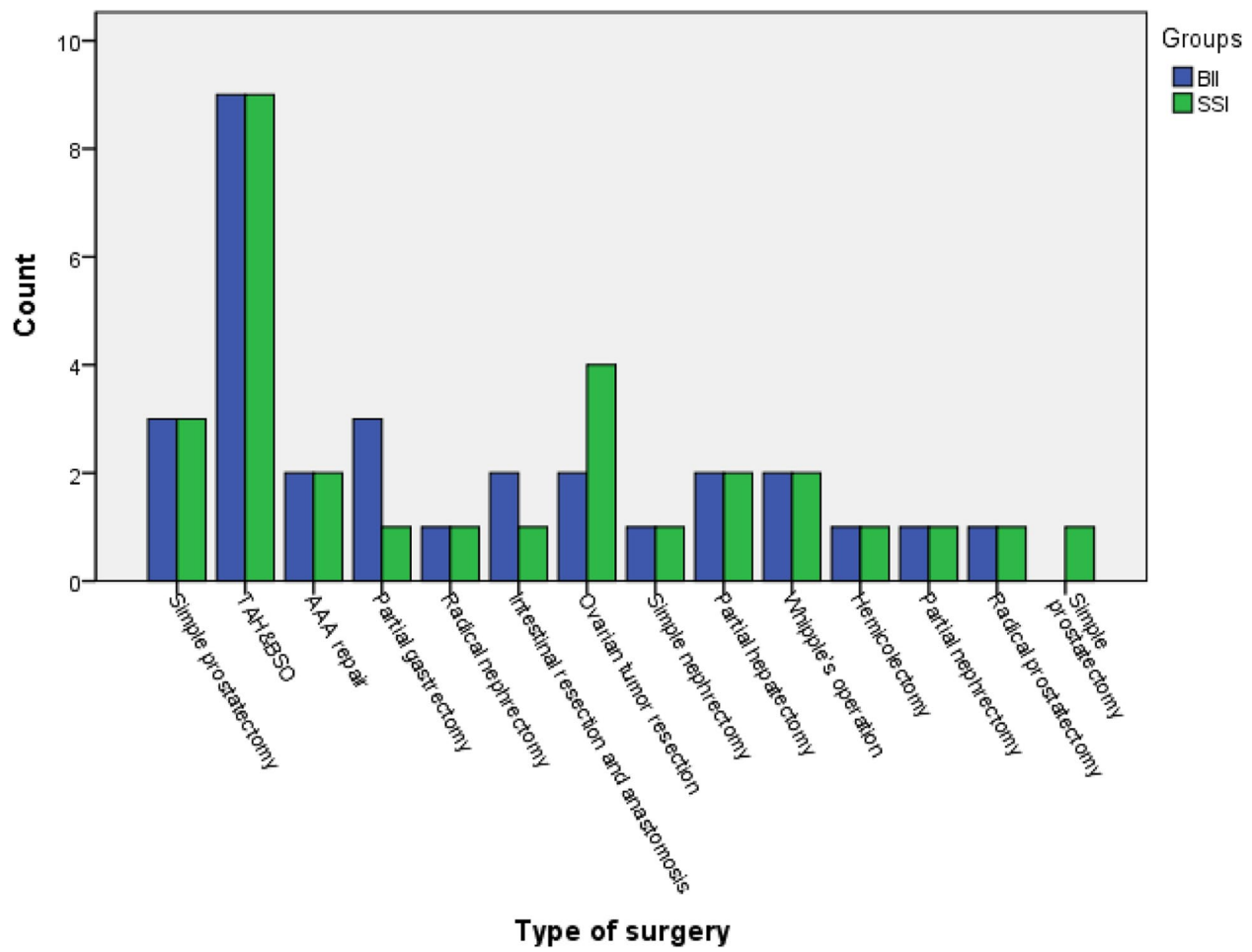

Fig. 2 Frequency distribution of the different types of surgeries. BII: Bolus-insulin infusion group, SSI: Sliding scale of insulin group

Table 1 Patients' demographic data

Variables	Groups		*P value*
	BII (*N* = 30)	SSI (*N* = 30)	
Age (years)	53.07 ± 9.1	54.97 ± 9.1	0.423
Sex (M/F)	13/17	12/18	0.793
Duration of surgery (min)	217 ± 54.4	205 ± 56.3	0.405

Data are presented as count and mean ± SD. *P* value > 0.05 is statistically non-significant. *BII* Bolus-insulin infusion group, *SSI* Sliding scale of insulin group, *M* Male, *F* Female

Table 2 Patients' laboratory results

Variables	Groups		*P value*
	BII (*N* = 30)	SSI (*N* = 30)	
HbA_1c (%)	6.46 ± 0.48	6.48 ± 0.43	0.845
Pre-operative FBG (mg/dl)	160.66 ± 65.81	157.86 ± 62.78	0.867
Pre-operative s. K (mEq/l)	4.03 ± 0.33	4.04 ± 0.33	0.877
Post-operative s. K (mEq/l)	3.64 ± 0.24	3.75 ± 0.32	0.141

Data are presented as mean ± SD. *P* value > 0.05 is statistically non-significant. *BII* Bolus-insulin infusion group, *SSI* Sliding scale of insulin group, *HbA1c* Glycosylated hemoglobin, *FBG* Fasting blood glucose, *s.k* Serum potassium

parameters. A two-way mixed ANOVA was conducted, to detect if there is any significant effect of the two approaches on mean s. K concentration over time (pre-operative versus post-operative). *P* value < 0.05 was considered statistically significant.

Results

Sixty patients (30 patients in each group) underwent elective laparotomy surgeries (Fig. 2), with statistically non-significant age, sex, and mean operative duration, with *P* value 0.423, 0.793 and 0.405 respectively were included in the study (Table 1). The pre-operative HbA_1c, FBG (Table 2) and baseline CBG (0 min) (Fig. 3) were comparable between the two groups with *P* value 0.845, 0.867 and 0.702 respectively.

The pre-operative and the post-operative s. K levels were comparable between the two groups, with *P* value 0.877 and 0.141 respectively (Table 2). Regarding the peri-operative changes in s. K levels, the time versus group test showed statistically non-significant relation; between the time of measurement of s. K (pre-operative and post-operative) and the type of approach (BII or SSI) on the mean s. K level (*P* value = 0.063). Also, the effects of the time of measurement (Within group) and the approach (between groups); showed statistically non-significant difference in the mean s. K level, with *P* value 0.877 and 0.425 respectively (Table 3).

Regarding the intra-operative CBG control, the CBG showed statistically significant decrease in the SSI group than in the BII group; starting from 30 minutes after the initial insulin given, then at 60, 90, 120, 150, 180, 210, 240 minutes and in the PACU, with *P* value 0.016, < 0.001, < 0.001, < 0.001, < 0.001, 0.008, 0.023, 0.034 and 0.003 respectively. There were no statistically significant differences between the two groups; with respect to the mean values of the CBG measured after 270 and 300 minutes, with *P* value 0.314 and 0.412 respectively (Fig. 3). No patient in either group developed hypoglycemia intra-operative or in the PACU.

Regarding the intra-operative achievement of the target CBG range, it was achieved by 50% of patients in the SSI group versus 46.7% of patients in the BII group (*P* value = 0.113) (Fig. 4). The mean intra-operative time needed to achieve the target CBG range was less in the SSI group than in the BII group, with statistically significant difference between the two groups (*P* value = 0.011) (Table 4). Regarding the mean percentage of operative time with the target CBG range, it was statistically non-significant higher in the SSI group (49.7 ± 28.1) than the BII group (54.6 ± 28.9) (95% confidence interval of the mean difference is 3.7 and 19.7 with *P* value = 0.503) (Fig. 5). Regarding the intra-operative decrease in CBG below the target range, it was statistically non-significant between the two groups (*P* value = 0.113), the maximum decrease in CBG was at 300 minutes, it was statistically non-significant between the two groups (*P* value = 0.412).

Regarding the achievement of target CBG range in the PACU, it was achieved by 40% of patients in the BII group versus 20% of patients in the SSI group, and this was statistically significant with *P* value 0.029. Regarding the drop below the target CBG range in the PACU, it was statistically significant between the two groups; 80% of patients in the SSI group versus 50% of patients in the BII group with *P* value 0.029, the mean CBG was statistically significant lower in the SSI group (*P* value 0.003) (Fig. 4). The rate of decrease in CBG/units insulin given was statistically non-significant between the two groups (*P* value = 0.299) (Table 4).

Regarding the insulin units given, the initial mean insulin units given in the SSI group was statistically significant more than that given in the BII group (*P* value < 0.001). Regarding the mean extra insulin units given, it was statistically non-significant more in the BII group (*P* value = 0.167). Regarding the mean total insulin units given, it was statistically non-significant more in the SSI group (*P* value = 0.695) (Table 5). No patient in the BII needed supplemental IV insulin bolus and infusion.

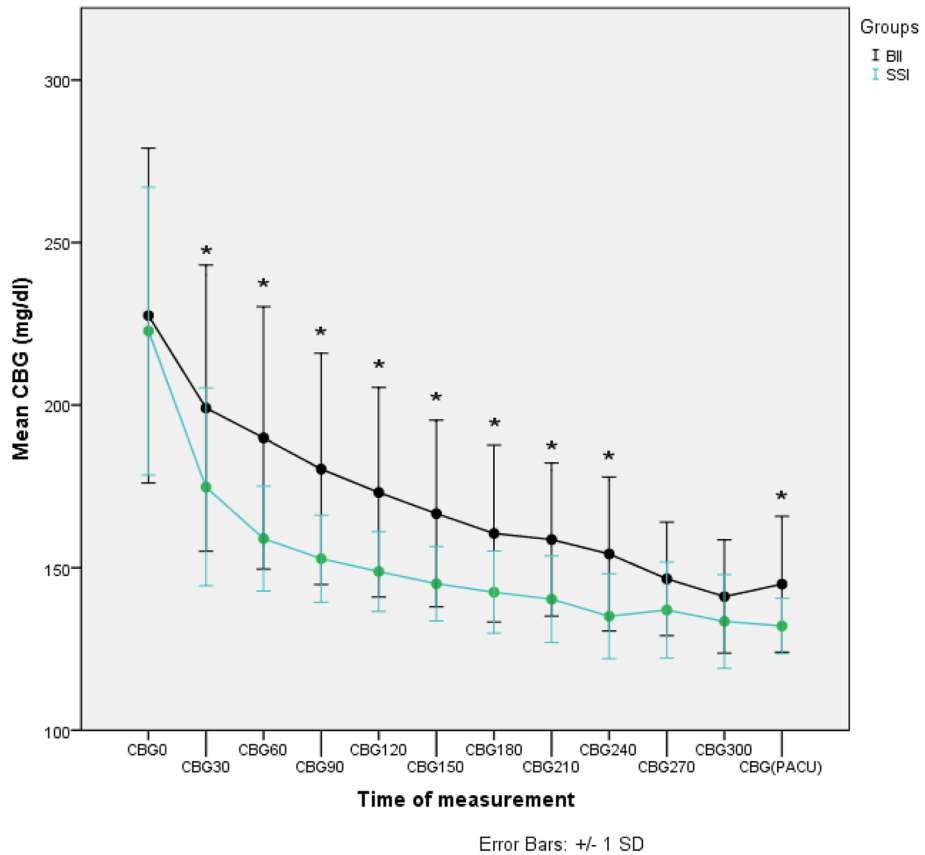

Fig. 3 The mean CBG at different times of measurement. Data are presented as mean ± SD. *P* value > 0.05 is statistically non-significant. BII: Bolus-insulin infusion group, SSI: Sliding scale of insulin group, CBG: Capillary blood glucose, PACU: Post anesthesia care unit

Table 3 The effect of the BII and the SSI approaches on the mean peri-operative s. K level

Tests of Within-subjects effects	F value	*P value*
Time versus group	4.792	0.063
Time (pre &post-operative)	0.024	0.877
Test of Between-subjects effects	F value	*P value*
Groups	0.646	0.425

P value > 0.05 is statistically non-significant

Discussion

Patients included in the current study were those with pre-operative FBG ˂ 350 mg/dl, and HbA_1c ˂8.5%. As, the recommendations of the Society for Ambulatory Anesthesia (SAMBA) is not to delay surgery for certain FBG (Joshi et al., 2010), and the 1 year mortality was independently associated with pre-operative FBG (Abdelmalak et al., 2013). Elective surgery is postponed with pre-operative $HbA_1c > 8.5\%$, and pre-operative HbA_1c ˂7% is associated with decreased post-operative infections (Raju et al., 2009). The pre-operative target was to avoid hyperglycemia, ketoacidosis, and hypoglycemia, and to maintain the fluid and electrolyte balance (Cosson et al., 2018).

The current study followed the approach, proposed by Bhamidipati and his colleagues in 2011 for intra-operative CBG ˃180 mg/dl; intermittent bolus or bolus-infusion of IV insulin with CBG measurement every 30–60 min.

In the present study, the SSI group showed statistically significant decrease in the intra-operative CBG than the BII group; starting from 30 minutes after the initial insulin given to 240 minutes, with statistically non-significant maximum decrease at 300 minutes between the two groups, with no patient in either group developing intra-operative hypoglycemia. The percentage of patients who achieved the intra-operative target CBG range, was statistically non-significant between the two groups, this is explained by the statistically non-significant difference in the rate of decrease in CBG/ insulin units given in the two groups. However, it was statistically significant achieved faster, with statistically and clinically non-significant higher mean percentage of operative time with the target CBG range; in the SSI group than in the BII group. This

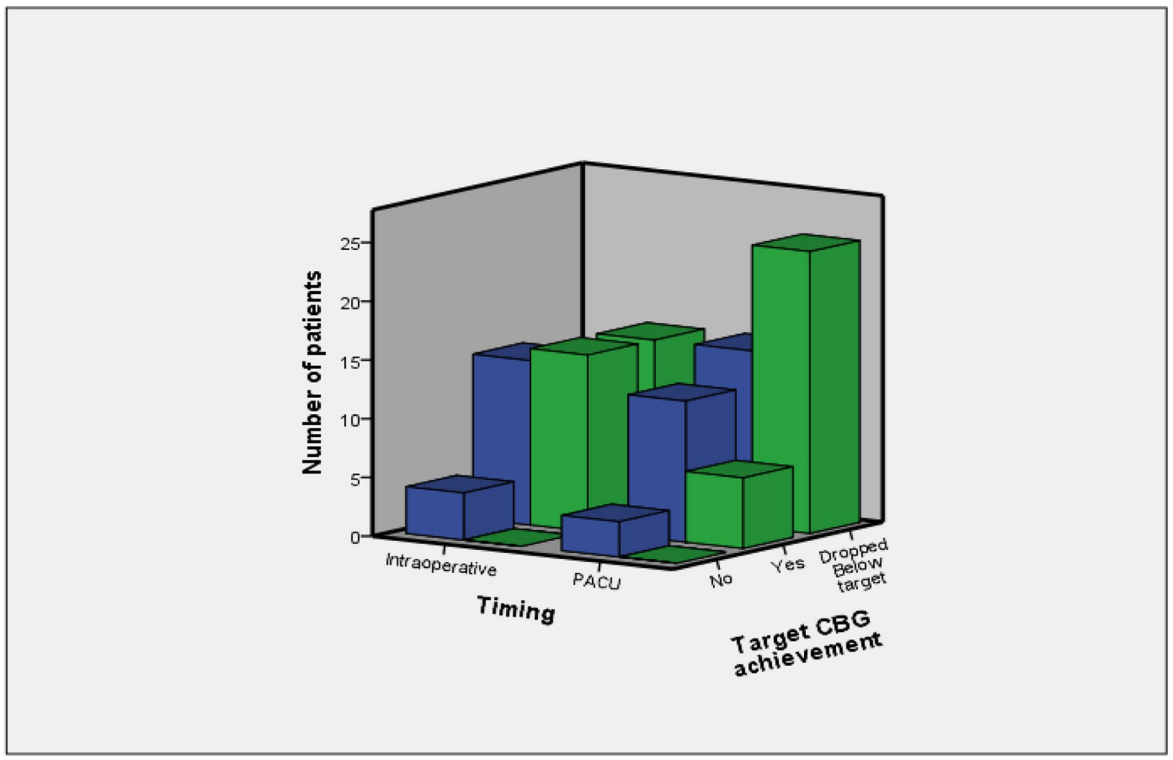

Fig. 4 Achievement of the target CBG intra-operative and in the PACU. Data are presented as number of patients. BII: Bolus-insulin infusion group, SSI: Sliding scale of insulin group, CBG: Capillary blood glucose, PACU: Post anesthesia care unit

Table 4 Time needed to achieve the target CBG and the rate of decrease in CBG

Variables	Groups		*P value*
	BII (*N* = 30)	SSI (*N* = 30)	
Time (min) needed to achieve the target CBG	70.4 ± 62.9	39 ± 16.1	0.011*
The rate of decrease in CBG/ insulin units given	17.2 ± 4.5	16.2 ± 2.6	0.299

Data are presented as mean ± SD. P value > 0.05 is statistically non-significant

*indicates statistical significance. *BII* Bolus-insulin infusion group, *SSI* Sliding scale of insulin group, *CBG* Capillary blood glucose

is attributed to the statistically significant higher initial mean insulin units, given in the SSI group than that given in the BII group, with immediate onset of action of rapid acting insulin, and peak effect at 10–15 minutes (Hirsch et al., 1991), and duration of action of 3–4 hours (Kroon et al., 2009), so, hypoglycemia is detected with 30 minutes CBG measurement (Krishna and Arun, 2019).

Our results go with those by (Monnier et al., 2006; Subramaniam et al., 2009), as they found the BII to have low CBG variations than the SSI with the same CBG target. BII for intra-operative CBG control was postulated by Abdelmalak in 2018. Also, Alberti and Thomas in 1979 and Hirsch and his colleagues in 1991 showed that; regular supply of small insulin units (1 IU/hr), offered stable insulin concentrations with better CBG control than 2 IU/hr., without the development of hypoglycemia or ketogenesis. However, Watts and his colleagues in 1987 reported 5–10% incidence of hypoglycemia with continuous insulin infusion, which was related to the insulin infusion rate. Decreased variation in CBG results in cardio-protective effect, decreased oxidative stress and cell damage (Hirsch and Brownlee, 2005; Egi et al., 2006). SSI with intermittent administration of large insulin units is un-physiologic. This roller coaster approach leads to extremely low insulin concentrations before giving the second insulin bolus, with unstable CBG level and ketogenesis (Hirsch et al., 1991).

Rapidly decreasing CBG level and varying degrees of surgical stress; result in greater variability in CBG level (Subramaniam et al., 2009), that is why adequate depth of anesthesia with avoidance of hypercapnia, with adequate analgesia by the thoracic epidural

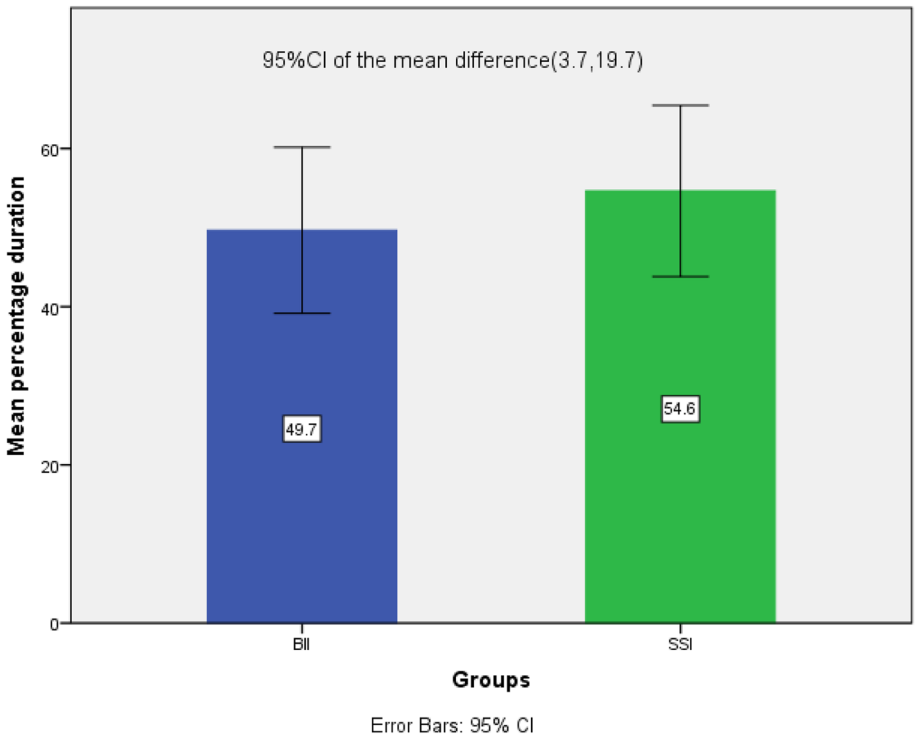

Fig. 5 The mean percentage of operative time with the target CBG range. BII: Bolus-insulin infusion group, SSI: Sliding scale of insulin group, CBG: Capillary blood glucose, CI: Confidence interval

Table 5 The insulin units given

Variables	Groups		*P value*
	BII (*N* = 30)	**SSI (*N* = 30)**	
Initially given Insulin (IU)	3.34 ± 0.78	4.66 ± 1.42	< 0.001*
Extra insulin given (IU)	2.13 ± 2.98	1.21 ± 2.14	0.167
Total insulin given (IU)	5.51 ± 3.74	5.87 ± 3.32	0.695

Data are presented as mean ± SD. *P* value > 0.05 is statistically non-significant. *indicates statistical significance. *BII* Bolus-insulin infusion group, *SSI* Sliding scale of insulin group, *IU* International units

inserted in the current study, are crucial for glycemic control. Also, our results are similar to those by Krishna and Arun in 2019, as the SSI approach provided glycemic control; in terms of target CBG range and intra-operative percentage time with the target CBG range. In the study by Watts and his colleagues in 1987, the BII resulted in 8% incidence of hyperglycemia, and 5% incidence of hypoglycemia, this may be attributed to the very frequent CBG measurement every 15 min.

In the PACU, the percentage of patients who achieved the target CBG range was statistically significant higher in the BII group, this is attributed to the statistically non-significant higher extra insulin units given in the BII group than the SII group. The percentage of patients with drop below the target CBG range; was statistically significant higher in the SSI group than the BII group, with statistically significant lower mean CBG in the SSI group, with no patient developing hypoglycemia. This is attributed to the statistically non-significant higher mean total insulin units given in the SSI group.

Insulin shifts K^+ intra-cellularly, by increasing the Vmax of the sodium/potassium ATPase (Na-K ATPase) pump, and promoting the translocation of Na-K ATPase from intra-cellularly to the cell membrane (Kamel et al., 2014). In the current study, there were no different effects of the two approaches on the mean peri-operative s. K level. Our results are explained by Kamel and Harel in 2016, who found that an insulin level of 500 IU/ml is required to achieve maximal K^+ shift (1.54 mmol /L). Ten IU insulin bolus resulted in, a mean decrease in s. K of 0.53 ± 0.25 mmol/L at 60 minutes. 20 IU insulin infusion for 60 minutes resulted in, a mean decrease in s. K of 0.85 ± 0.06 mmol/L. Also, our results go with those by Alberti and Thomas in 1979, which showed stable s. K concentration with 1 IU/hr. insulin infusion.

Conclusions

For type 2 diabetes mellitus patients, undergoing operations more than 148 minutes, the BII approach slowly achieves the intra-operative conservative CBG target range; in terms of the mean percentage of the operative time with the target range, and the percentage of patients. This achievement continues in the PACU, with less percentage of patients with decreased CBG below the target range.

Abbreviations

ASA: American Society of Anesthesiologists; BII: Bolus insulin infusion; CBG: Capillary blood glucose; DPP-4: Dipeptidyl peptidase − 4; ECG: Electrocardiography; FBG: Fasting blood glucose; HbA_1c: Glycosylated hemoglobin; IU: International units; IV: Intra-venous; NPH: Neutral protamine Hagedorn; NIBP: Non-invasive blood pressure; NS: Normal saline; PACU: Post anesthesia care unit; s.k: Serum potassium; SSI: Sliding scale of insulin; SGLT-2: sodium glucose co-transporter-2; NHE-1: Sodium/ hydrogen exchanger-1; Na-K ATPase: Sodium/potassium ATPase; SC: Subcutaneously..

Acknowledgments

Not applicable.

Authors' contributions

MG designed the study, revised literature and reviewed the manuscript. GS design of the work, revised literature, performed the analysis, revised the statistical analysis and wrote the manuscript. DA followed the patients, collected the data. All authors approved the final version of the manuscript. All authors have contributed intellectually to the manuscript and the manuscript has been read and approved by all the authors. The manuscript has not been published, simultaneously submitted or accepted for publication elsewhere.

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Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available [publishing the clinical data about any study conducted in our hospitals and approved by the institutional ethical committee is against the policy of the Faculty of Medicine, Ain Shams University unless there is a reasonable request] but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Approval of research ethical committee of Faculty of Medicine, Ain-Shams University was obtained (FMASU R16/2021) and written informed consent was obtained from the patients after description of the procedure. The study was registered with Clinical Trials Registry (NCT05136157) on 20/10/2021.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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