

A COMPARATIVE STUDY BETWEEN OXYTOCIN INTRAVENOUS BOLUS VERSUS OXYTOCIN INTRAVENOUS BOLUS AND INFUSION FOR CONTROL OF BLOOD LOSS AT ELECTIVE CESAREAN SECTION

By

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ABSTRACT

Background: Postpartum hemorrhage following vaginal birth or cesarean section birth and constitute a serious health problem and are associated with increased risk of maternal morbidity and mortality. Almost all of these maternal deaths could be avoided if complications are diagnosed early and treated appropriately.

Objective: To assess the value of additional oxytocin infusion and bolus versus bolus only in control of blood loss during cesarean section and its role in prevention of major obstetric hemorrhage.

Patients and Methods: In this study, 200 pregnant females at 38-40 weeks gestation were recruited from Al-Hussein and Sayed Galal hospital, Al-Azhar University Maternity hospitals (Patients admitted for elective cesarean section). Routine full blood count was performed before operation on admission and 48 hours after delivery to assess hemoglobin and hematocrit.

Results: As regards patients received oxytocin bolus only; it was found that a significantly higher prevalence of patient receiving additional uterotonics in this group in comparison to patient receiving oxytocin bolus and oxytocin infusion. As regards occurrence of major obstetric hemorrhage we found no change in patient receiving oxytocin bolus only and patient receiving bolus and oxytocin infusion showed no significant difference between both groups as regards patient developed side effects. Also, no significant difference as regards patient developed severe anemia.

Conclusion: additional oxytocin infusion (40 IU oxytocin in 500 mL of saline solution over the next four hours at a rate of 125 mL/h) after 5 mL i.v. oxytocin infusion at elective cesarean section may reduce need of additional uterotonics.

Key words: Oxytocin, intravenous, infusion, blood loss elective Cesarean section.

INTRODUCTION

Cesarean delivery is defined as the birth of a fetus through incision in the abdominal wall (laparotomy) and the uterine wall (hysterotomy). This definition does not include removal of the fetus from the abdominal cavity in case of rupture

uterus or in the case of an abdominal pregnancy (*Sung and Mahdy, 2019*).

Cesarean section rates had increased steadily in both developed and developing countries beyond recommended percentages by World Health Organization (10–15 %) (*ACOG, 2019*).

Although cesarean delivery greatly improves obstetric outcomes when clinically indicated, excessively high Cesarean delivery rates have raised concern about the health and economic consequences of this practice (*Magne et al.*, 2017). In China, it approaches 46% in 2011. In Egypt it reaches 29.5% in 2011 (*Kirchengast and Hartmann*, 2019).

The rising rates of primary cesarean sections have resulted in a large population with scarred uteri and in subsequent pregnancies these women are risk-prone (*Elebrashy et al.*, 2011).

Major obstetric hemorrhage (more than 35% blood loss) continued to be one of the most common cause of direct maternal death (more than half of cases of maternal death) in obstetric practice (*Shivakumar et al.*, 2013).

The management of bleeding in cesarean section is a shared responsibility between obstetricians and anesthetists, Different figures varying from less than 500 ml to more than 1000 ml have been quoted as estimation of blood loss associated with cesarean section. There is also a wide variation in blood ordering practices for this surgery. Several factors like habit, training and medico-legal concerns may be responsible in addition to difficulty in blood loss assessment in Cesarean sections (*Aksoy et al.*, 2015).

The use of an uterotonic drug immediately after the birth of the newborn is one of the most important actions used to prevent postpartum hemorrhage (PPH). Many considerations are selecting these uterotonic agents as cost, Efficacy, stability, response time, adverse effects, contraindications, requirements for

administering the drug (*Gallos et al.*, 2018).

The golden point when using oxytocin or any other uterotonic drug is to obtain satisfactory uterine tone by least amount to reduce side effects of the uterotonic agents (hypotension, nausea, emesis) and to reduce time for establishment and maintenance of adequate uterine tone (*Vallera et al.*, 2017).

Oxytocin is the most common uterotonic drug used to control, prevent and treat postpartum hemorrhage (PPH). The value of routine oxytocics in the third stage of vaginal birth has been well established and it has been assumed that these benefits apply to cesarean delivery as well. Royal College of Obstetrics and Gynecology (*RCOG*, 2014) recommend a slow i.v bolus dose of oxytocin following delivery of the baby at cesarean section. Some clinicians use an additional infusion of oxytocin for a further period following the procedure. Intravenous oxytocin has a very short half-life (4–10 minutes) therefore the potential advantage of an oxytocin infusion is that it maintains uterine contractility throughout the surgical procedure and immediate postpartum period, when most primary hemorrhages occur (*Güngördük et al.*, 2018).

Use of lowest effective dose of oxytocin may decrease side effects. The bolus dose of oxytocin used at elective cesarean deliveries in non-laboring women can be significantly reduced while maintaining effective uterine contraction. Alteration in practice will likely reduce the potential adverse effects of this drug when given in large bolus doses, but may require modification of the techniques to

remove the placenta (*Bhattacharya et al., 2013*).

The aim of this study was to compare the intravenous slow bolus of oxytocin versus the intravenous slow bolus of oxytocin and oxytocin infusion on control of blood loss at elective cesarean section.

PATIENTS AND METHODS

Two hundred healthy women were recruited from the outpatient clinic in Al-Hussein and Sayed Galal hospitals, Al-Azhar University. The patients will be admitted in the inpatient ward of both hospitals for elective cesarean section. All females included in the study gave written consents after explanation of the nature of the study.

The study included women with singleton pregnancies, aged >17 years, with gestational age ranging from 38-40 weeks calculated from the first day of the last normal menstrual period and no medical complications (cardiac, renal, hypertensive, diabetic disorders).

Women with previous major obstetric hemorrhage, patients at risk of postpartum hemorrhage (PPH): Previous history of PPH, Placenta praevia/acreta (history of antepartum hemorrhage), oversized uterus e.g twin pregnancy, polyhydramnious, uterine fibroid and bleeding tendency e.g (anticoagulant therapy, idiopathic and thrombocytopenic purpura (ITP), women with more than previous three cesarean sections, intervention that lengthen the operation e.g ovarian cystectomy, incisional hernia repair and tubal ligation, trial of labor and preterm labor were excluded from the study.

The females subjected to this study were divided into the following equal groups: Group (A) received an intravenous slow bolus of oxytocin 5 IU and a placebo infusion (0.9% saline solution 500 ml over 4 hours), and Group (B) received oxytocin bolus 5 IU and oxytocin infusion (40 units in 500 ml 0.9% saline over 4 hours).

All females in the study were subjected to detailed history taking to obtain data regarding patients age, parity and number of previous cesarean section, general examination, ante-natal investigations (Rh, complete blood picture, PT, PTT, INR and PC), fasting and postprandial blood sugar and complete urine analysis), full blood count 48 hours after delivery to assess hemoglobin and hematocrit, developing of severe anemia >20 % reduction in Hb.

Cases were followed after delivery, stay in theatre and recovery room to ensure continuity of infusion, and to detect uterine atony, development of early lochial loss, postpartum hemorrhage and any side effects of oxytocin, serial clinical examination, blood pressure and pulse measurements.

Oxytocin bolus 5 IU and oxytocin infusion (40 IU oxytocin in 500 mL saline infused over four hours) were compared with 5 IU oxytocin bolus and placebo infusion (500 mL saline infused over 4 hours).

Randomisation took place after patients consented to participation in the study. We used an automated web based randomization system ensuring allocation concealment. Allocation was stratified by centre and previous cesarean section (no/yes), and blocked by use of random

permuted blocks of varying size. We randomly assigned women to receive either an intravenous slow bolus of oxytocin 5 IU over 1 minute and 40 IU oxytocin in 500 mL of 0.9% saline solution over 4 hours (bolus and infusion), or an oxytocin bolus 5 IU over 1 minute and 500 mL of 0.9% saline solution over 4 hours (2.5ml/min bolus only).

Anesthesia was standardized. An intravenous bolus of 500 ml crystalloid was given to all patients prior to spinal anesthesia. Intravenous crystalloids were continued at 1 liter every 8 hours until the morning after surgery, unless the patient was unable to tolerate oral fluids.

Surgical approach to cesarean section was standardized. Surgeons were asked to operate to a standard procedure that specifies controlled cord traction for delivery of the placenta after administration of the oxytocin bolus, two layer closure of the uterine incision, and to avoid delivering the uterus for suturing unless clinically indicated.

An objective measure of blood loss was calculated using pre- and post-operative hematocrit (EBL cal Calculated estimated blood loss). The estimate was calculated as follows:

$$\text{EBL} = (\text{EBV} \times (\text{Pre-op Hct} - \text{Post-op Hct})) / \text{Pre-op Hct}$$

Where EBV estimated blood volume = Booking weight in kg x 85.

Blood loss at operation was replaced with colloid infusion or blood. Postoperative pain relief consisted of regular non-steroidal analgesia combined with paracetamol. Vital signs were monitored. Clinical follow-up of the mother was completed prior to hospital discharge.

Study protocol was submitted for approval by the Ethical Committee of faculty of Medicine, AL-Azhar University.

Statistical analysis:

Recorded data were analyzed using the statistical package for the social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as range, mean \pm standard deviation (SD). Qualitative data were expressed as frequency and percentage. The following tests were done: Mann-Whitney U test was used when comparing between two means. Chi-square (χ^2) test of significance was used in order to compare proportions between qualitative parameters. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value <0.05 was considered significant.

RESULTS

Two patients had blood transfusion in group (A) and 8 developed severe anemia 6 patients in group (A) and one patient in group (B), 34 patients need Additional uterotonic 22 patients in group (A) and 12 patients in group (B) Demographic and

clinical characteristics of the studied groups: the mean age of group (A) was 31.63 years and group (B) was 30.97.

No statistically significant difference was found between groups according to their baseline characteristics regarding

age, GA, number previous CS and parity, with p-value >0.05 (Table 1).

Table (1): Comparison between group A and group B according to baseline characteristics (n=200)

Baseline characteristics	Group A (n=100)	Group B (n=100)	p-value
Age (years)			
Range	19-43	18-45	> 0.05
Mean±SD	31.63±7.55	30.97±7.79	
GA (wks)			
Range	38-41	38-41	> 0.05
Mean±SD	38.44±1.04	38.48±0.89	
Number Previous CS			
Range	0-3	0-3	> 0.05
Mean±SD	0.79±1.05	1.05±1.03	
Parity			
≥2	52 (52%)	56 (56%)	> 0.05
<2	48 (48%)	44 (44%)	

No statistically significant difference between groups according to their adherence to surgical protocol and adherence to anesthetic protocol, with p-value >0.05. The study revealed no statistically significant difference between groups according to previous pelvic surgery, with p-value >0.05. A statistically

significant difference was found between groups regarding add. Uterotonics, there were 22 cases Yes (22.9%) and 74 cases No (77.1%) of group A, also were 12 cases Yes (12.2%) and 86 cases No (87.8%) of group B regarding Add. Uterotonics, with p-value <0.05 (Table 2).

Table (2): Comparison between group A and group B according to adherence to surgical protocol and adherence to anesthetic protocol, previous pelvic surgery and add. uterotonics (n=200).

Parameters	Group A (n=100)	Group B (n=100)	p-value
Adherence to surgical protocol			
Yes	88 (88%)	92 (92%)	> 0.05
No	12 (12%)	8 (8%)	
Adherence to anesthetic protocol			
Yes	96 (96%)	88 (88%)	0.037
No	4 (4%)	12 (12%)	
Previous pelvic surgery			
Yes	8 (8%)	10 (10%)	> 0.05
No	92 (92%)	90 (90%)	
Add. Uterotonics			
Yes	22 (22.9%)	12 (12.2%)	> 0.05
No	74 (77.1%)	86 (87.8%)	

The study showed no statistically significant difference between groups according to estimated blood loss and hemorrhage, with p -value >0.05 . There was no statistically significant difference between groups according to their mean of Hb. pre-operative in group A 10.88 ± 0.97 compared to group B 11.13 ± 1.17 , with p -value >0.05 . While no statistically significant difference between groups according to their mean of Hb. post-

operative in group A 10.22 ± 1.08 compared to group B 10.60 ± 1.20 , with p -value >0.05 . Also no statistically significant difference between groups according to their difference in pre and post-operative by Hb. in group A 0.66 ± 0.25 compared to group B 0.53 ± 0.16 , with p -value >0.05 . There was no statistically significant difference between groups according to their severe anemia, with p -value >0.05 (**Table 3**).

Table (3): Comparison between group A and group B according to estimated blood loss, hemorrhage, hematocrit and severe anemia (n=200)

Parameters \ Groups	Group A (n=100)	Group B (n=100)	p-value
Estimated blood loss	840.65 \pm 397.56	547.51 \pm 222.15	> 0.05
Hemorrhage			
>1000	16 (16.7%)	6 (6.1%)	> 0.026
<1000	80 (83.3%)	92 (93.9%)	
Preoperative (n=200)			
Range	8.08-13.13	7.98-13.86	> 0.05
Mean \pm SD	10.88 \pm 0.97	11.13 \pm 1.17	
Post-operative (n=194)			
Range	6.84-12.92	7.51-13.23	> 0.05
Mean \pm SD	10.22 \pm 1.08	10.60 \pm 1.20	
Difference in maternal pre and post-operative	0.66 \pm 0.25	0.53 \pm 0.16	> 0.05
Severe anemia			
>20%	8 (8.3%)	2 (2.0%)	0.047
<20%	88 (91.7%)	96 (98.0%)	

There was no statistically significant difference between groups according to their shows side effects of oxytocin, with p -value >0.05 . There was no statistically significant difference between groups according to their mean of postnatal length of stay in (theatre) in group A 45.84 ± 17.06 compared to group B

44.74 ± 9.64 , with p -value >0.05 . While no statistically significant difference between groups according to their mean of postnatal length of stay in recovery room in group A 16.48 ± 6.15 compared to group B 15.45 ± 5.63 , with p -value >0.05 (**Table 4**).

Table 4): Comparison between group A and group B according to shows side effects of oxytocin, postnatal length of stay in theater and postnatal length of stay in recovery room

Shows side effects of oxytocin	Group A (n=96)	Group B (n=98)	p-value
No	76 (79.2%)	78 (79.6%)	0.631
Hypotension	6 (6.3%)	8 (8.2%)	0.139
Nausea	6 (6.3%)	6 (6.1%)	0.751
Vomiting	8 (8.3%)	6 (6.1%)	0.572
Postnatal length of stay in (theatre)	45.84±17.06	44.74±9.64	0.449
Postnatal length of stay in recovery room	16.48±6.15	15.45±5.63	0.530

DISCUSSION

In many countries, cesarean section (C/S) has become the mode of delivery in over a quarter of all births. It is the most commonly performed operation in obstetrics (*Singh et al., 2018*).

In this study, we choose to follow the recommendation in 2004 of Royal College of Obstetricians and Gynaecologists (*RCOG, 2014*). Guideline on cesarean section recommends a slow intravenous bolus dose of 5 IU of oxytocin following delivery of the infant.

We debated the choice of primary outcome and decided on two outcomes, both reflecting uterine atony. Major obstetric hemorrhage is the most relevant clinical outcome because it is a leading cause of maternal death worldwide.

We measured total blood loss at the time of cesarean section but chose a calculation based estimate, based on preoperative and postoperative packed cell volume as a primary outcome in the interests of objectivity. The measured blood loss would be more relevant in resource poor settings where blood tests are not routinely performed.

In this study, the mean age of group A was 29.48 years and group B was 28.86. The difference was statistically insignificant. Also, there was insignificant difference between both groups as regarding maternal weight, gestational age (GA).

Our results showed no significant difference in both group as regarding number of previous cesarean section. This result was in accordance with the study done by *Gungorduk and Colleagues (2010)*.

The difference was statistically insignificant between both groups as regarding vascularity of lower segment, adherence to surgical protocol, adherence to anesthetic protocol, parity ≥ 2 , history of previous pelvic surgery. This indicates that both groups were almost identical statistically and gave statistical value to our results. This result was in accordance with the initial large study by *Sheehan and Colleagues (2011)*.

Results of the current study showed higher need for additional uterotronics in group A compared to group B. The difference was statistically significant.

Similar to our results, were obtained by *Sheehan et al. (2011)*.

Also, *Güngördük et al. (2010)* found that there were more women in the placebo group who needed additional uterotonic agents than in the oxytocin group, and this difference was statistically significant.

However, unlike to our results, *King et al. (2010)*, in a small trial, investigated the effects of a placebo bolus and oxytocin infusion compared with an oxytocin bolus and oxytocin infusion, and found no difference in the need for an additional uterotonic agent in the first 24 hours after cesarean section.

Comparison between group A and group B regarding estimated blood loss mean value during cesarean section was statistically insignificant. Similar to our results, *Sheehan et al. (2011)* compared the effects of a 5-IU oxytocin bolus and placebo infusion versus a 5-IU oxytocin bolus and 40 IU infusion and found that no statistical difference between both group as regarding mean blood loss (587 ml) compared to (583 ml).

Unlike our results, *Güngördük et al. (2010)* found that mean blood loss after 5 IU oxytocin and 30 IU oxytocin in 500 mL of lactated Ringer's solution administration was less than after 5 IU oxytocin and 500 mL of lactated Ringer's solution administration. However, different methods of estimating blood loss limits direct comparison with other studies.

Our results showed no statistical difference between both groups as regarding occurrence of major obstetric hemorrhage >1000ml. Similar to our

results, *Sheehan et al. (2011)* found no difference in the occurrence of major obstetric hemorrhage between the groups. They reported that women were less likely to have a major obstetric hemorrhage in the bolus and infusion group than in the bolus only group if the obstetrician was junior rather than senior.

Unlike our results, *Güngördük et al. (2010)* found that after 5 IU oxytocin and 30 IU oxytocin in 500 mL of lactated Ringer's solution administration, the percentage of patients with blood loss >1000 mL and required blood transfusion were less with infusion group.

Owonikoko et al. (2011), compared the effectiveness of oral misoprostol and intravenous oxytocin in reducing blood loss in women undergoing indicated or elective cesarean delivery under spinal anesthesia, in prospective, double-blind pilot study. They stated that oxytocin followed by oral misoprostol is as effective as an oxytocin injection followed by an oxytocin infusion in reducing postoperative blood loss after cesarean delivery, and the protocol may be a safe, valuable, and cost-effective alternative to oxytocin alone. Visual estimation of intraoperative blood loss undervalues the effective value of misoprostol use was by 30%.

The golden point when using oxytocin or any other uterotonic drug is to obtain satisfactory uterine tone by least amount to reduce side effects of the uterotonic agents (hypotension, nausea, emesis), and to reduce time for establishment and maintenance of adequate uterine tone (*Yamaguchi et al., 2016*).

There was a statistical insignificance between both groups regarding numbers

of cases develop side effects (SE) of uterotonic drugs. The results in this study showed use of oxytocin infusion after an initial bolus did not increase the occurrence of side effects of oxytocin (hypotension, nausea and vomiting). Our results showed patients developed hypotension (3/48) in bolus only group comparing to (4/49) in bolus and infusion group. Patients developed nausea (3/48) in bolus only group comparing to (3/49) in bolus and infusion group. Patients developed vomiting (4/48) in bolus only group comparing to (3/49) in bolus and infusion group this was statistically insignificant. This result was in accordance of *Sheehan et al. (2011)* where they found no side effects in infusion and bolus group, 20.1% in bolus and infusion group comparing to 18.0% in bolus only.

Similar to our results, *Güngördük et al. (2010)* found no statistical difference in the incidence of uterotonic side effects between the two groups.

There was a statistical insignificance between both groups regarding difference in maternal pre and post-operative hematocrit (drop in hematocrit) mean value. Similar to our results, *Sheehan et al. (2011)* compared the effects of a 5-IU oxytocin bolus and placebo infusion versus a 5-IU oxytocin bolus and 40 IU infusion, and they found no significant difference drop in hematocrit. Unlike our results, *Güngördük et al. (2010)* found a statistically significant lower postoperative hematocrit level in placebo group.

There was a statistical insignificance between both groups regarding difference in maternal pre and post-operative Hb% (drop in Hb%) mean value.

Unlike our results, *Güngördük et al. (2010)* found statistically significant lower postoperative hemoglobin level in placebo group.

There was a statistical insignificance between both groups regarding number of cases developed severe anemia. Like our result, *Sheehan et al. (2011)* found no significant difference between both groups as regard number of patients developed severe anemia.

There was a statistical insignificance between both groups regarding postnatal length of stay in theatre and recovery room respectively. Like our result, *Sheehan et al. (2011)* found no significant difference between both groups as regarding postnatal length of stay in theatre and recovery room respectively.

Butwick et al. (2015) agreed that the initial period after placental delivery during CS is important in terms of bleeding risk. Early assessment and confirmation of adequate uterine tone is vital in potentially reducing the risk of post-partum hemorrhage. As a result, they set a primary time point for assessment at 2 min after oxytocin injection. The use of low doses of oxytocin as an infusion may result in a significant time-delay in achieving the initial uterotonic effect, as the half-life of oxytocin is 5–12 min and metabolic clearance rates are high leading to higher postnatal hospital stay.

Unlike our results, *Güngördük et al. (2010)* found that mean length of hospital stay was longer in the placebo group than in the oxytocin group, which was also statistically significant.

CONCLUSION

Additional oxytocin infusion (40 IU oxytocin in 500 mL of saline solution over the next four hours at a rate of 125 mL/h) after 5 mL i.v. oxytocin infusion at elective cesarean section may reduce need of additional uterotonics.

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دراسة مقارنة للحقن الوريدي للأوكسيتوسين مقابل الحقن الوريدي بالإضافة إلى محلول الأوكسيتوسين للسيطرة على فقدان الدم في الولادات القيصرية الاختيارية

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خلفية البحث: يشكل النزيف ما بعد الولادة عن طريق المهبل أو ما بعد الولادة القيصرية مشكلة خطيرة تزداد معها معدلات المضاعفات المرضية وارتفاع نسبة الوفيات لدى الأمهات. ومن الممكن منع نسبة كبيرة من تلك الحالات بالتشخيص المبكر للمضاعفات والعلاج المناسب.

الهدف من البحث: تحديد فائدة إعطاء الحالات دواء الأوكسيتوسين عن طريق جرعة بالوريد وجرعة بالتنقيط الوريدي مقارنة بإعطاء الحالات جرعة الأوكسيتوسين عن طريق الوريد فقط للتحكم بفقدان الدم أثناء الولادة القيصرية الاختيارية. ودوره في منع حدوث نزيف ما بعد الولادة في الحالتين، والذي يؤدي بدوره في المستقبل للوقاية المبكرة والعلاج التدخل لتحسين الصحة الإنجابية، وتقليل معدلات المضاعفات المرضية الخطيرة وحالات الوفيات لدى الأمهات.

المرضى وطرق البحث: أجريت تلك الرسالة على 200 سيدة من الحوامل في الأسابيع من 38-40 أسبوع حمل واللاتي تم حجزهن للولادة القيصرية الاختيارية بمستشفى أمراض النساء والتوليد (مستشفيات السيد جلال والحسين بجامعة الأزهر) وتم شرح تفاصيل الدراسة لهن وأخذ موافقتهن للمشاركة بها وقد استكمل المتابعة 194 سيدة فقط حتى الولادة.

نتائج البحث: وجد أن 17 سيدة تم إعطاءهن أدوية إضافية مقبضة للرحم منهن 11 سيدة بالمجموعة الأولى مقابل 6 سيدات بالمجموعة الثانية مما له دلالة إحصائية ذات مغذى. ولم توجد اختلافات بين المجموعتين في نسبة حدوث نزيف شديد بعد الولادة. كما لم تظهر نتائج الدراسة اختلافاً بين المجموعتين في نسبة

حدوث أعراض جانبية لدواء السينتوسينون. وأيضاً لم تُظهر الدراسة اختلاف بين المجموعتين من حيث حدوث أنيميا حادة (فقر بالدم).

الاستنتاج: إضافة الأوكسيتوسين (بجرعة 40 وحدة دولية من الأوكسيتوسين في 500 مل من محلول ملحي خلال الأربع ساعات التالية بمعدل 125 مللتر) بعد 5 مل عن طريق الوريد قد يقلل من الحاجة إلى مقويات توتر الرحم الإضافية في حالات الولادة القيصرية الاختيارية.

الكلمات الدالة : أكسيتوسيني – الحقن الوريدي – فقد الدم – القيصرية .