INTRODUCTION

Cesarean section is the delivery of a baby through a surgical abdominal incision ***(Josef et al., 2003)***. Cesarean section (CS) rates have increased to as high as 25 to 30 % in many areas of the world ***(Kambo et al., 2002)***.

Delivery by CS can cause more complications than normal vaginal delivery. Infection can occur at the incision site, in the uterus and in other pelvic organs such as the bladder. There is more blood loss in a cesarean delivery than with a vaginal delivery. This can lead to anemia or a blood transfusion (1 to 6 women per 100 require a blood transfusion). Possible injury to organs such as the bowel or bladder. Scar tissue may form inside the pelvic region causing blockage and pain. Adhesions can also lead to future pregnancy complications such as placenta previa or placental abruption. Extended hospital stay and recovery time. There can be a negative reaction to the anesthesia given during a cesarean or negative reaction to pain medication given after the procedure. Risk of additional surgeries: Includes possible hysterectomy, bladder repair or another cesarean. Risks and complications for the baby e.g; premature birth breathing problems, low APGAR scores and fetal injury may occur ***(American Pregnancy Association, 2013).***

One of the most common complications is primary or secondary postpartum hemorrhage (20%). It leads to increased maternal mortality and morbidity. Postpartum hemorrhage causes approximately 25% of maternal deaths worldwide (WHO Recommendations 2006) and 12% of survivors will have severe anemia ***(Abou Zahr, 2003).***

In order to reduce maternal mortality and morbidity caused by bleeding, it is important to reduce the amount of bleeding during and after lower segment cesarean section (LSCS).

In severe cases, CS may result in major obstetric hemorrhage, hysterectomy, admission to an intensive care unit, or maternal death. Medications, such as oxytocin, misoprostol, prostaglandin F2α, and tranexamic acid, have been used to control bleeding after CS ***(Güngördük et al., 2010).***

Tranexamic acid is a synthetic derivative of the amino acid lysine that exerts its antifibrinolytic effect through the reversible blockade of the lysine binding sites on plasminogen molecules. Intravenous administration of tranexamic acid has been routinely used for many years to reduce hemorrhage during and after surgical procedures like coronary artery bypass, oral surgery, orthotopic liver transplantation, total hip or knee arthroplasty, and urinary tract surgery ***(Ido et al., 2000).***

Tranexamic acid has been shown to be very useful in reducing blood loss and incidence of blood transfusion in these surgeries. Tranexamic acid is inexpensive and treatment would be considered highly cost effective in high, middle and low income countries ***(Guerriero et al., 2011).***

In this study, the efficacy and safety of tranexamic acid in the reducing the blood loss during and after elective LSCS will be investigated.

AIM OF THE STUDY

To state the effectiveness clinically, laboratory and safety of tranexamic acid in reducing blood loss during and after the elective lower segment cesarean section.

Study question

Is tranexamic acid effective in reducing blood loss during and after the elective lower segment cesarean section?

Study hypothesis

Null hypothesis: amount of blood loss during and after cesarean section does not change with use of tranexamic acid.

CAESAREAN SECTION

Caesarean delivery also known as a C-section is a surgical procedure used to deliver a baby through an incision in the mother's abdomen (laparotomy) and a second incision in the mother's uterus (hystrotomy). This definition does not include removal of the fetus from the abdominal cavity in cases of uterine rupture nor in cases of abdominal pregnancy ***(Cunningham et al., 2007).***

Caesarean deliveries may be performed because of maternal or fetal problems that arise during labor, or they may be planned before the mother goes into labor ***(Vincenzo et al., 2010).***

An emergency CS is defined as one where this mode of delivery had not been anticipated and where it was preceded in labor either spontaneous or induced which was deliberately allowed to continue for a time. All other C.S were defined as elective procedure ***(Lurie et al., 2003).***

Caesarean section rates:

The World Health Organization (WHO) recommends that the rate of caesarean sections should not exceed 15% in any country (World Health Organization 2009). However, in recent years the rate has risen to a record level of 46% in

china and to levels of 25% and above in many Asian countries, Latin America and the USA ***(WHO, C. Section rates around Globe, 2010).***

Caesarean section rates in Egypt:

Regarding Egypt, a significant rise in caesarean deliveries has been occurred for all births from a low of 4.6% in 1992 to 10.3% in 2000. however, hospital- based caesarean deliveries were much higher in 1988 (13.9%), increasing to 22.0% in1999 to 2000. Although the caesarean section rate was slightly higher in private hospitals, the rate also increased consistently in public hospitals. This high increase in caesarean section rates may be due to caesarean sections that are not medically indicated, and suggest that physician practice patterns, financial incentives or other profitability factors, and patient preferences should be explored ***(Khawaja et al., 2004).***

Indications of Caesarean Sections

Caesarean sections (C/S) are classified to elective and urgent or emergency. Elective or planned C/S are performed according to an antepartum indication and at a time to suit the patient and the maternity team. Urgent C/S are performed after labor onset, mostly due to failure to progress or fetal compromise, which is not immediately life threatening.

Emergency C/S is performed when there is an immediate threat to the woman or fetus ***(Ylva et al., 2010).***

Caesarean section is recommended when vaginal delivery might pose a risk to the mother or baby. A caesarean delivery is performed for maternal indications or fetal indications, or both. The leading indications for caesarean delivery are previous caesarean delivery, breech presentation, dystocia, and fetal distress. These indications are responsible for 85% of all cesarean deliveries ***(Cunningham et al., 2000).***

I. Maternal Indications

Cesarean delivery has been advocated for various maternal diseases. Traditionally it has been to advocate cesarean delivery for congenital or acquired cardiac disease, but current evidence favours vaginal delivery, especially in the presence of maternal pulmonary vascular disease where the operative delivery significantly worsens the prognosis ***(Connolly et al., 1999).***

Maternal diabetes in pregnancy has been associated with increased rates of cesarean section ***(Boulvain et al., 2000).*** Other maternal diseases, such as idiopathic thrombo-cytopenic purpura (I.T.P.) and obstetric cholestasis, are also

associated with increased rates of cesarean section to avoid fetal morbidity and mortality ***(Fisk et al., 1998).***

Similarly, in pre-eclampsia there is a higher risk of cesarean section, with some authors describing cesarean section rates over 80% in gestation below (30) weeks with sever pre-elampsia ***(Magann et al., 2002).***

Mothers with an incompetent cervix in whom vaginal cervical cerclage have failed should have a cesarean delivery ***(Cunningham et al., 2000).***

In the presence of major placental abruption (i.e abruption is large but less than 50% and fetal distress more than 90%), even when the fetus is alive at presentation and the uterus is rigid, the outlook for the fetus is poor and immediate delivery by cesarean birth is usually recommended ***(Chamberlain et al., 2001).***

Diagnosis of placenta previa is usually an indication for delivery by cesarean section. However, if the previa is of a minor degree (type I-II) and the fetal head is engaged, trial of vaginal delivery may be attempted. Cesarean section is the recommended mode of delivery in major placenta previa (type III-IV) ***(Chamberlain et al., 2001).***

Vasa Previa is a rare condition that carries a high fetal mortality resulting from tearing of the fetal vessels when they lie within the membranes. Trans-vaginal ultrasonography and color doppler may be used for diagnosis of vasa previa, and elective cesarean section is recommended for these cases ***(Oyelese et al., 1999).***

Childbearing is an established risk factor for urinary incontinence among Young and middle-aged women ***(Rortveit et al., 2003).*** Vaginal delivery represents a potent determinant of stress urinary incontinence, carrying more than twice the risk of cesarean section ***(Goldberg et al., 2005).***

Caesarean delivery on maternal request refers to caesarean delivery performed because the mother requests this method of delivery in the absence of conventional medical or obstetrical indications for avoiding vaginal birth. The right to be actively involved in treatment decisions including method of delivery is now widely accepted by physicians and patients ***(Coleman et al., 2010).***

A high rate of women wish to give birth by caesarean section. This is probably an expression of the changes in society's attitudes. This wish is correlated with patient's age > 35 years, high level of education, previous infertility,

smoking, quality of information, and desire for more comprehension ***(Mancuso et al., 2006).***

Benefits of elective CS. may include avoiding certain risks related to vaginal delivery (urinary or rectal incontinence, sexual dysfunction, dystocia), avoiding labor pains, alleviation of fear and anxiety related to labor or birth ***(Hildingsson et al., 2002).***

However, serious consequences for subsequent pregnancies like uterine rupture or placenta previa, which may be associated with accreta or abruption of the placenta, are of major concern ***(Schneider et al., 2002).***

Caesarean section also requires a longer recovery time and operative complications such as lacerations and bleeding may occur, at rates varying from 6% for elective caesarean to 15% for emergency caesarean ***(Bergholt et al., 2003).***

The cesarean delivery should be done in the presence of obstructive lesion in lower genital tract, including malignancies and large vulvo-vaginal condyloma ***(Cunningham et al., 2001).***

Cesarean delivery should be done in women with contracted pelvis due to old fracture or congenital deformity or large sized fetal head ***(Cunningham et al., 2009).***

Women with prior vaginal colporraphy, repair of vesico-vaginal fistula and major anal involvement from inflammatory bowel disease are candidates for an elective cesarean section ***(Cunningham et al., 2003).***

II. Fetal Indications

Fetal indications for cesarean delivery include those in which neonatal morbidity and mortality could be decreased by the prevention of trauma, infection, and prolonged hypoxia.

III. Caesarean Section for Previous Caesarean Section

One of the most common indications for cesarean section is previous cesarean section. When the most common cesarean section was the classical cesarean section, clinicians feared scar rupture in attempting normal vaginal delivery and repeat cesarean section was considered mandatory for all subsequent births. However, it rapidly became clear that lower segment cesarean section was not associated with dangerous ruptures and the concept of trial of normal vaginal delivery became current ***(Landon et al., 2007).***

Complications of CS

A. Fever, Infection, Pneumonia, and Thrombo-embolic Events

The risk of these types of postpartum morbidity is consistently increased with the caesarean delivery. Most studies on postpartum morbidity were limited to inpatients and did not account for women who experienced complications after hospital discharge **(Declercq E, 2007).**

B. Surgical and Traumatic Complications

Include damage to the bladder, ureters, and other abdominal structures. According to the National Institute of Health, weak evidence supported a lower risk of surgical complications with elective CS when compared to planned vaginal birth **(Rogers R, 2007).**

C. Rupture of a previous uterine scar

The patients who most frequently run into this rare complication are those who have had previous CS, but the surgeon must not forget those patients who have had hysterotomy, plastic procedures on the uterus or previous myomectomy **(Allen V, 2003)**.

D. Maternal Mortality

In June of 2006, the World Health Organization released the results of a 2005 survey of maternal and

perinatal health, with attention to the rising rate of caesarean delivery. Data from almost 100,000 deliveries in Latin America reflected higher rates of severe maternal morbidity and mortality when compared to vaginal delivery, even after adjusting for risk **(Villar J, 2005).**

E. Hemorrhage

Primary post-partum hemorrhage (PPH) is defined as blood loss greater than or equal to 500 ml within 24 hours after birth, while severe PPH is blood loss greater than or equal to 1000 ml within 24 hours***(WHO guidelines for the management of postpartum hemorrhage and retained placenta, 2009).*** Secondary PPH is defined as abnormal or excessive bleeding from the birth canal between 24 hours and 12 weeks post-natally ***(Alexander et al., 2002).***

PPH can be classified to minor (500-1000 ml) or major (more than 1000 ml).Major could be divided to moderate (1000-2000 ml) or severe (more than 2000 ml) ***(Mousa, 2007).***

According to national statistics in Egypt, Hemorrhage before and after delivery was the leading direct cause of maternal death (43%), with most hemorrhage deaths due to postpartum hemorrhage. There were 32 maternal deaths with hemorrhage per 100,000 live births. Figures for other causes

were much less than hemorrhage (e.g. hypertensive diseases were 18 per 100,000, for sepsis 7 per 100,000, for ruptured uterus 7 per 100,000, for cesarean section 6 per 100,000, for obstructed labor 4 per 100,000, for cardiac disease 11 per 100,000 and for anemia 9 per 100,000). ***(The National Maternal Mortality Study: Egypt 2000).***

Although The National Maternal mortality study found that maternal mortality has declined dramatically in Egypt; from 174/100,000 live births in 1992-93 to 84/100,000 in 2000, there is a place for improvement. This remarkable achievement of more than 50% decrease is indication for Egypt' s efforts to improve the quality of obstetric care, increase access to family planning, educate women and families about seeking prompt medical care for problems during pregnancy and labor. ***(The National Maternal Mortality Study: Egypt 2000).***

However, there were significant regional differences in maternal mortality, with the highest levels of maternal death occurring in the frontier governorates (i.e. Sinai and the deserts that lie west and east of the Nile) and the lowest levels in Metropolitan Egypt (i.e. Cairo, Alexandria) ***(The National Maternal Mortality Study: Egypt 2000)***

Table (1): Female deaths, maternal deaths, and maternal mortality ratios by region and governorate, 2000.

Region, Governorate	Live births	Female Deaths (FD) sample	Pregnancy related Deaths	Maternal Deaths (MD)	%MD/ FD	MMR	Confidence Limits LCL	UCL
Total	1,752,562	8497	639	585	6.9	84	80	89
Metropolitan	282,196	1,844	71	59	3.2	48	40	56
Lower Egypt	725,936	2,845	225	208	7.3	93	86	100
Upper Egypt	717,773	3,713	328	303	8.2	89	82	96
Frontier	26,657	95	15	15	15.8	120	78	161
Suez	11,460	78	11	10	12.8	87	33	141
Kafr El Sheikh	57,879	494	37	35	7.1	60	40	80
Beni Suef	61,468	379	43	41	10.8	67	46	87
Fayoum	66,851	418	36	34	8.1	51	34	68
Qena	80,965	647	49	49	7.6	61	44	77
Assiut	101,768	1,024	67	61	6.0	60	45	75
Luxor	10,798	90	9	9	10.0	83	29	138
Aswan	23,305	203	18	17	8.4	73	38	108
New Valley	4,283	15	1	1	6.7	23	0	69

(The National Maternal Mortality Study: Egypt 2000).

In the triennium 2006-2008, 261 women in the UK died directly or indirectly related to pregnancy. The overall maternal mortality rate was 11.39 per 100,000 maternities. Direct deaths decreased from 6.24 per 100,000 maternities in 2003-2005 to 4.67 per 100,000 maternities in 2006-2008 (p = 0.02). The number of deaths from postpartum hemorrhage (PPH) has halved to five. ***(Centre for Maternal and Child Enquiries (CMACE), BJOG 118, 2011).***