Uterine Tamponade with Condom Catheter Balloon in the Treatment of Atonic Postpartum hemorrhage: A Randomized Controlled Trial

Thesis

Submitted for Partial Fulfillment of Master Degree
In Obstetrics and Gynecology

By

Mohamed Mosaad Abdelfatah Shahat Omar

M.B.B.Ch 2012
Faculty of Medicine - Ain Shams University

Under Supervision of

Prof. Moustafa Ibrahim Ibrahim

Professor of Obstetrics and Gynecology
Faculty of Medicine - Ain Shams University

Dr. Amr Ahmed Mahmoud Riad

Lecturer of Obstetrics and Gynecology
Faculty of Medicine - Ain Shams University

Faculty of Medicine
Ain Shams University
2017

بسم الله الرحمن الرحيم

سورة البقرة الآية: ٣٢

Acknowledgments

Thanks are all to ***Allah****, The Compassionate and the Merciful, for helping me finish this work, and for blessing me throughout my life by His Compassion and Generosity.*

Words fail to express my great indebtedness to ***Professor/ Moustafa Ibrahim Ibrahim,*** *Professor of Obstetrics and Gynecology, Ain Shams University, whose continuous supervision, advice and fruitful criticism have been of great help in performing this work, and from whom I always learn a lot of lessons in my whole life.*

I would like to express my sincere appreciation to ***Doctor/ Amr Ahmed Mahmoud Riad,*** *Lecturer of Obstetrics and Gynaecology, Ain Shams University, for his continuous guidance, patience, experienced advice and great encouragement which has been of the most valuable and to whom I will always be indebted.*

Last but not least I would like to express my best regards and thanks to all who gave me a hand while working on this research and I'd like to dedicate this work to my beloved ***Family*** *who supported me to complete this work.*

Mohamed Mosaad Abdelfatah

List of Contents

List of Abbreviations

Abbr.	Title
APTT	Activated partial thromboplastin time
BMI	Body mas index
CBC	Complete blood count
CCT	Controlled cord traction
C°	Degree centigrade
FDA	Food and Drug Administration
FFP	Fresh frozen plasma
G.A	Gestational age
Gm	Gram
Hb%	Hemoglobin concentration
HCV	Hematocrit value
ICU	Intensive care unit
INR	International Normalized Ratio
IU	International unit
IV	Interavenous
Kg	Kilogram
L	Liter
µ.g	Micro gram
min	Minute
MmHg	Millimeter mercury
MOHP	Ministry of health and population
mL	Milliliter
MRI	Magnetic resonance imaging
NO	Nitric oxide
NSAID	Non-steroidal anti-inflammatory drug
PCV	Packed cell volume
PGS	Prostaglandins
PPH	Postpartum hemorrhage

RBC	Red blood cell
RCOG	Royal College of Obstetricians and Gynaecologists
SBOC	Sengstaken-blackmore oesophageal catheter
SAE	Selective Arterial Embolization
SPCERH	Scottish Programme for Clinical Effectiveness in Reproductive Health
SOS	Surgical Obstetric Silicone
TT	Thrombin time
OXY	Oxytocin
VDAC	Vaginal delivery after cesarean
WHO	World Health Organiztion
3rd	Third

List of Tables

List of Figures

Introduction

In low-resource countries, postpartum hemorrhage (PPH) is the leading cause of maternal mortality, and more than 30% of maternal deaths are attributed to PPH ***(Khan et al., 2006).***

The risk of maternal death from PPH in developing countries is approximately 1 per 1000 deliveries ***(Selo-Ojeme, 2002).***

Uterine atony is the most common cause of PPH and accounts for 79% of all PPH ***(Haeri and Dildy, 2012; Bateman et al., 2010).***

Whatever the cause of PPH, death should be preventable, and outcome is largely dependent upon timely interference and efficiency and vigor of medical practitioners. Active management of the third stage of labor reduces uterine atony and is the mainstay of prevention of hemorrhage ***(Prendiville et al., 2000).***

The management of uterine atony is well known and based on international guidelines. First-line treatment includes immediate uterine massage and administration of uterotonic drugs. The second-line treatment of uterine atony includes artery embolization and surgery interventions with uterine, ovarian and finally internal iliac artery ligation or hysterectomy ***(WHO, 2009).***

Significant variations in PPH management between countries have been observed based on the availability of resources. Uterine artery embolization is often unavailable in developing countries. Artery ligation via laparotomy and hysterectomy are the most common invasive procedures, but these interventions have high case fatality rates due to limited capacity for surgery, obstetrics, and anesthesia ***(Lalonde, 2012).***

The intrauterine balloon tamponade was recently incorporated into the strategy to manage uterine atony if bleeding is not stopped by pharmacological treatments ***(World health Organization 2009; Royal College of obstetricians and gynaecologists 2009).***

There are many types of tamponades including the foley's catheter, the condom catheter, the sengstaken-blackmore oesophageal catheter (SBOC), the rush urological hydrostatic balloon and the bakri ballon has been used. Among them, the condom catheter seems to be an efficient and economic intervention for the treatment of PPH in low resource countries ***(Tindell et al., 2012; Bagga et al., 2007; Rather et al., 2010).***

A latex condom is inserted into the uterus by a Foley catheter and inflated with solute. The reported success rate is 96% in a systematic review of observational studies in low-resource countries, and this could reduce the risk of invasive procedures ***(Thapa et al., 2010; Airede and Nnadi, 2008).***

Aim of the Work

The aim of this study is to assess the efficacy of uterine tamponade using condom catheter balloon in treatment of atonic postpartum hemorrhage.

Chapter (I)
Postpartum Hemorrhage

The mean duration of human singleton pregnancy is 280 days (forty weeks) calculated from the first day of the last menstrual period. Term" is defined as the period from the end of 37 weeks to the end of 42 weeks of gestation. "Preterm" labor refers to the onset of labor prior to the end of 37 weeks of gestation. "Postterm" pregnancy refers to pregnancies continuing beyond the end of 42 weeks of gestation ***(Cunningham et al., 2001).***

Physiology

Over the course of a pregnancy, maternal blood volume increases by approximately 50%, from 4 to 6 liters. The plasma volume increases somewhat more than the total red blood cell (RBC) volume, leading to a fall in the hemoglobin concentration (Hb%) and hematocrit (packed cell volume; PCV) values. This decrease is less frequent in women who take supplemental iron, whereas the fall may be dramatic in women who do not take supplemental iron, who have limited iron stores, or are anemic upon becoming pregnant.

The increase in blood volume serves to fulfill the perfusion demands of the low-resistance uteroplacental unit and to provide a reserve for the blood loss that occurs at delivery. The increased blood volume also protects against hypotension

caused by decreased venous return and decreased vascular tone due to high progesterone levels ***(Baskett, 1999).***

Changes also occur in the coagulation system, with a marked increase in clotting factors and a decrease in fibrinolytic activity. The platelet count may fall slightly during pregnancy because of dilution related to the increased plasma volume and as a result of low-grade consumption; however, individual platelet volume is increased and activity is maintained. Although uterine contraction is initially responsible for controlling blood loss at the placental site, clot formation and fibrin deposition occur rapidly and are essential in maintaining hemostasis and promoting involution in the days following delivery ***(Sleep, 1993).***

Early in pregnancy, the uterus grows dramatically, from an initial weight of roughly 70 gm and a cavity volume of 10 mL to a term weight of 1.1 kg and a capacity of approximately 5 litres. As with the hematological and coagulation changes, high levels of estrogen promote and allow this change in the uterus ***(Cunningham et al., 2001).*** The initial growth of the uterus and the ultimate growth of the placenta and fetus require an equally impressive increase in blood flow to the uterus during pregnancy. At term, the estimated blood flow to the uterus is 500-800 mL/min, which

represents 10-15% of cardiac output. Most of this flow traverses the low-resistance placental bed ***(Baskett, 1999).***

Labor at term may be regarded physiologically as a release from inhibitory effects of pregnancy on myometrium rather than as an active process mediated by uterine stimulants. However, it is likely that both inhibitory and stimulatory mechanisms are important ***(Lopez et al., 1995).*** Labor is the physiologic process by which a fetus is expelled from the uterus to the outside world. Labor is defined as an increase in myometrial activity or, more precisely, a switch in the myometrial contractility pattern from "contractures" (long-lasting, low-frequency activity) to contractions" (frequent, high-intensity, high-frequency activity) ***(Nathanielsz et al., 1997),*** resulting in effacement and dilatation of the uterine cervix ***(Duff et al., 1984).***

In normal labor, there appears to be a time-dependent relationship between the biochemical connective tissue changes in the cervix, which usually precede uterine contractions and cervical dilatation. All of these events usually occur before rupture of the membranes ***(Duff et al., 1984).***

Following delivery of the fetus, uterine contractions continue and the placenta is sheared from the underlying endometrium. This separation primarily occurs by a reduction in the surface area of the placental site as the uterus shrinks