EVALUATION OF OBSTETRIC SHOCK INDEX IN IDENTIFYING OUTCOME OF PRIMARY POSTPARTUM HAEMORRHAGE

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LIST OF ABBREVIATIONS

ACOG	American College of Obstetricians and Gynaecologist
AUROC	Area Under the Receiver Operating Characteristic curve
BMI	Body mass index
DBP	Diastolic blood pressure
DIVC	Disseminated intravascular coagulation
EBL	Estimated blood loss
HR	Heart rate
HUSM	Hospital Universiti Sains Malaysia
ICU	Intensive care unit
JEPEM	The Human Researh Ethics Committee of USM
MEWS	Modifies Early Warning Score
PC	Packed cells
PP	Pulse pressure
PPH	Postpartum hemorrhage
RCOG	Royal College of Obstetricians and Gynaecologists
SBP	Systolic blood pressure
SD	Standard deviation
SI	Shock index
SIRS	Systemic Inflammatory Response Syndrome
SPSS	Statistical Package for the Social Sciences
SVD	Spontaneous vaginal delivery
WHO	World Health Organization

ABSTRACT

Objective: To determine relationship between obstetric shock index and outcomes of primary postpartum haemorrhage. This study also aimed to determine proportion of blood transfusion, surgical intervention and ICU admission in relation to shock index.

Methods: A retrospective cohort study which was conducted in the Obstetrics and Gynaecology Department, Hospital Sultan Ismail Johor Bahru. We reviewed 607 women who delivered vaginally at term from January 2015 till December 2020, with estimated blood loss of more than 500 mL. The highest shock index within 2 hours after onset of PPH is used for analysis. Adverse outcomes such as requirement of blood transfusion, surgical intervention (Bakri balloon, EUA and perineal repair, compression suture, arterial ligation and hysterectomy) and ICU admission were reviewed.

Result: From this study, 607 women that had blood loss more than 500 mL were analysed but only 513 women met the inclusion criteria. However, 88 women had missing data thus only 425 women included in this study. Out of 425 women, majority of the race are Malay ethnicity (79.1%). Mean age is 29.4 years old (SD=5.47), majority are multiparity (57.2%) and BMI 25-29.9kg/m2^2 (33.4%). Most common mode of delivery in this study are spontaneous vaginal delivery (69.9%). Most of postpartum haemorrhage started immediately after the birth (96.7%), 64.7% required blood transfusion, 11.3% required surgical intervention and 3.1% required ICU admission. The most common cause of PPH was uterine atony (59.8%) and there was 1 case of maternal mortality. There is significant difference (P<0.001) in obstetric shock index 1.2 that required blood transfusion compared to obstetric shock index 0.8 that did not required blood transfusion, obstetric shock index 1.1 that required surgical intervention compared to obstetric shock index 0.9 that did not required surgical intervention and obstetric shock index 1.8 that required ICU admission compared to obstetric shock index 0.9 that did not required ICU admission. The proportion of patients required blood transfusion is 35.3%, getting surgical intervention is 10.8% and admitted to ICU is 4.3%. Shock index consistently more accurate to predict requirement of blood transfusion 95% (93-98%), surgical intervention 76% (68-83%) and ICU admission 96%, (93-99%). The obstetric shock index ≥0.9 is a good predictor all adverse outcomes, except ICU admission. Obstetric shock index ≥1.8 showed a potentially severe outcome and need ICU admission.

Conclusion: From this study, we conclude that SI consistently is a strong predictor of adverse clinical outcomes. We propose threshold of SI ≥0.9 is to alert medical personnel and require prompt action, SI ≥1.1 require intervention such as blood transfusion and surgical intervention while SI ≥1.8 is potentially severe outcome of patient that require ICU admission.

Keywords: Postpartum haemorrhage, obstetric shock index, obstetric shock index

ABSTRAK

Objektif: Untuk mengenal pasti hubungan di antara indek kejutan dan kesan terhadap pendarahan selepas kelahiran. Kajian ini juga bertujuan mengenal pasti populasi di antara pesakit yang memerlukan penambahan darah, pembedahan dan kemasukan ke unit rawatan rapi berdasarkan kepada indek kejutan.

Rekabentuk kajian: Ini adalah kajian retrospektif yang dijalankan di Jabatan Obstetrik dan Ginekologi, Hospital Sultan Ismail Johor Bahru. Kami menilai sebanyak 513 pesakit yang melalui proses kelahiran biasa bermula Januari 2015 sehingga Desember 2020, dengan anggaran kehilangan darah melebihi 500 mL. Indek kejutan tertinggi yang dicatat dalam masa 2 jam bermula dari tempoh pendarahan selepas kelahiran akan diambil. Kesan sampingan seperti penambahan darah, pembedahan dan kemasukan ke unit rawatan rapi akan dinilai.

Keputusan: Berdasarkan kajian ini, sebanyak 607 pesakit yang mengalami pendarah melebihi 500 mL selepas kelahiran dinilai tetapi hanya 513 pesakit yang memenuhi kriteria yang diperlukan. Walaubagaimanapun, sebanyak 88 pesakit dikecualikan kerana kehilangan data, oleh itu hanya 425 pesakit dinilai di dalam kajian ini. Purata tertinggi adalah dari bangsa Melayu (79.1%), berumur di antara 21 hingga 30 (52.9%), multipariti (57.2%) dan BMI 25-29.9kg/m2^2 (33.4%). Kelahiran tertinggi adalah kelahiran secara normal (69.9%). Kebanyakkan pesakit kehilangan darah bermula dari proses kelahiran (96.7%). 67.3% pesakit diberi cecair resussitasi, 64.7% memerlukan transfusi darah, 11.3% memerlukan pembedahan dan 3.1% memerlukan kemasukan ke unit rawatan rapi. Penyebab utama kehilangan darah semasa proses kelahiran adalah rahim tidak mengecut (59.8%) dan terdapat 1 kes kematian ibu. Terdapat perbezaan yang ketara ($P<0.001$) di mana indek kejutan kelahiran 1.2 memerlukan penambahan darah berbanding indek kejutan kelahiran 0.8 yang tidak memerlukan penambahan darah, indek kejutan kelahiran 1.1 memerlukan pembedahan berbanding indek kejutan kelahiran 0.9 yang tidak memerlukan pembedahan, dan indek kejutan kelahiran 1.8 memerlukan kemasukan ke unit rawatan rapi berbanding indek kejutan kelahiran 0.9 yang tidak memerlukan kemasukan ke unit rawatan rapi. Populasi pesakit yang memerlukan penambahan darah adalah 35.3%, memerlukan pembedahan 10.8% dan kemasukan ke unit rawatan rapi 4.3%. Indek kejutan lebih tepat meramal keperluan untuk penambahan darah 95% (93-98%), pembedahan 76% (68-83%) dan kemasukan ke unit rawatan rapi 96% (93-99%). Indek kejutan ≥0.9 tepat untuk menilai kesemua kesan sampingan dari kehilangan darah kecuali kemasukan ke unit rawatan rapi. Indek kejutan kelahiran ≥1.8 menunjukkan kebarangakalian kesan buruk yang akan terjadi terhadap pesakit.

Kesimpulan: Berdasarkan kajian ini, kami memutuskan bahawa indek kejutan kelahiran adalah factor yang kuat dan tepat untuk meramal kesan sampingan yang bakal berlaku. Kami memutuskan indek kejutan kelahiran ≥0.9 memberi amaran kepada pegawai perubatan, index kelahiran ≥1.1 memerlukan tindakan awal seperti transfusi darah dan pembedahan manakali indek kejutan kelahiran ≥1.8 meramalkan kesan buruk yang bakal berlaku dan memerlukan kemasukan ke unit rawatan rapi.

1. INTRODUCTION

Primary postpartum hemorrhage (PPH) is a major cause of maternal morbidity. It affects almost 5-6% of all pregnancies and is the principal cause of maternal deaths in both developed and developing countries (Carroli G, Cuesta C, Abalos E, Gulmezoglu AM, 2008). In Malaysia, it was recorded as the principal cause of maternal death in year 2019 as 17.5%, followed by obstetric embolism (12.6%), eclampsia (9.7%), ectopic pregnancy (5.8%) and puerperal sepsis (5.8%) (Statistic causes of death, Malaysia 2019). Most death or severe morbidities in primary postpartum hemorrhage are due to delays in identifying and managing the hemodynamically unstable patients. The morbidity and mortality rates are higher if patients delivered in district hospital, as attended by unskilled and inexperienced attendants thus delayed the intervention and as well as referral and transportation to tertiary centre.

Postpartum hemorrhage has been categorized as primary and secondary. This classification is based on timing of occurrence. Primary PPH is defined when the hemorrhage occurs within the 24 hours of delivery while secondary PPH has been defined as hemorrhage that occur between 24 hours postpartum and up to 12 weeks postpartum. Primary PPH has been classified when women loss blood more than 500ml during vaginal delivery or more than 1000ml during caesarean birth, within 24 hours after delivery. However, there are other multiple criteria used for diagnosis of primary PPH worldwide, as show in table below (Table 1). As most of primary PPH are diagnosed by clinical estimation blood loss, however studies have shown that we are usually underestimate blood loss and may cause delay in diagnosis and intervention (Diaz V, Abalos E, Carroli G, 2018). Additionally, postpartum morbidity and mortality are relatively infrequent among women with blood loss 500 to 999 mL (Anger H, Durocher J, Dabash R, Winikoff B, 2019).

WHO	Blood loss ≥500 mL within 24 hours after birth. Severe PPH: Blood loss ≥1000 mL within the same time frame.
ACOG	Cumulative blood loss ≥1000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process (includes intrapartum loss) regardless of route of delivery.
RCOG	Minor PPH (500 to 1000 mL) and major PPH (>1000 mL). Subdivisions of major PPH include moderate (1001 to 2000 mL) or severe (>2000 mL).
International expert panel (Abdul Kadir R et al, 2014)	Active bleeding >1000 mL within the 24 hours following birth that continues despite the use of initial measures, including first-line uterotonic agents and uterine massage.
Society of Obstetricians and Gynaecologists of Canada	Any amount of bleeding that threatens the patient's hemodynamic stability.
California Maternal Quality Care Collaborative	Stage 0: Every woman in labor/giving birth. Stage 1: Blood loss >500 mL after vaginal or >1000 mL after cesarean delivery; or change in vital signs >15% or heart rate ≥110 beats/minute, blood pressure ≤85/45 mmHg, O_2 saturation <95%. Stage 2: Continued bleeding with total blood loss <1500 mL. Stage 3: Total blood loss >1500 mL or >2 units packed red cells transfused; or unstable vital signs; or suspicion of disseminated intravascular coagulation.

Table 1. Example criteria used for primary PPH

In obstetrics, visual estimation of blood loss during delivery is commonly practiced however it is inaccurate. This unfortunately resulted in delay diagnosis and management of PPH. In order to facilitate timely recognition and treatment, early warning criteria have been proposed. In which, one or more abnormal parameters to escalate care in managing PPH or sepsis (Maguire PJ, O’Higgins A, Power K, 2014). Early warning systems such as the Systemic Inflammatory Response Syndrome (SIRS) or Modified Early Warning Score (MEWS) that have been used in non-obstetrics case however have poor predictive abilities in obstetric cases. This is due to significant physiological changes during pregnancy and labor (Edwards SE, Grobman WA, Lappen JR, et al, 2015). Hence, we need a more simple, reliable and useful tool for early detection for primary PPH that allows additional attention and intervention.

Shock index (SI) is calculated as heart rate (HR) divided by systolic blood pressure (SBP). It was first introduced in year 1967 by Allgower and Burri. It was initially used as an early marker to detect hemodynamically unstable and hypovolemia primarily in emergency medicine (Mutschler, M., Nienaber, U., Münzberg, M., 2013). Currently, it is also widely used in obstetric for blood loss estimation and indicator to initiate treatment for PPH (Takeda S, Makino S, Takeda J, Kanayama N, 2017). Recent studies have shown that shock index is useful and accurate in predicting adverse maternal outcomes of PPH, this includes need for blood transfusion, intensive care unit (ICU) admission as well as death among women, compared with traditional tools such as heart rate and blood pressure alone (Nathan HL, El Ayadi A, Hezelgrave NL, Seed P, 2015). Nowadays, we can find many available guidelines that emphasize the usage of SI in detecting PPH, as well as evaluate its severity and efficacy of the management (Mavrides E, Allard S, Chandranharan E, Collins P, Green L, RCOG Green top guideline. Prevention and management of PPH, 2017). However, these guidelines did not provide specific value of shock index to detect adverse outcomes of PPH.

Many questions regarding shock index that are used during vaginal delivery remained unanswered (Pacagnella, R. C., Souza, J. P., Durocher, J., Perel, P., 2013); trend of shock index during PPH that require early detection and treatment, correlation between shock index and blood loss, as well as whether SI is an optimal parameter to detect adverse outcomes of PPH. It is hoped that this study will help to understand how SI might facilitates in early detection and treatment of PPH. Hence, a concise manual guideline concerning PPH can be formulated which may help out current practice and improve the outcome of the patients.

2. LITERATURE REVIEW

2.1 Prevalence and incidence

Primary postpartum hemorrhage remains a principal cause of maternal morbidity and mortality (Oyelese, Yinka MD, Ananth, Cande V., 2010), with majority of the cases occur during delivery and the immediate postpartum period (Campbell OM, Graham WJ, 2006). It affects 5-6% of all pregnancies and is the leading cause of approximately 25% of all maternal death worldwide, in both developed and developing countries (Carroli G, Cuesta C, Abalos E, Gulmezoglu, 2008). Incidence of primary PPH has consistantly rising in UK, 13.8% in year 2012-2013 (Hospital Episode Statistics NHS Maternity Statistics, England, 2013–2014, 2015) and is the third leading cause of maternal death (Knight M, Kenyon S, Brocklehurst P, 2014). In low income countries, it is stated about 80% of maternal deaths are related to postpartum hemorrhage (Kassebaum NJ, Barber RM, Bhutta ZA, 2016).

While in Japan, incidence of massive PPH that with blood loss more than 2000 mL is 1.1% (Kamei Y, Kubo T, Yano T., 2009) and women that had life threatening PPH is estimated to occur in one of every 1000 births (Drite J. Management of PPH, 1997). In France, maternal mortality due to postpartum hemorrhage has decreased (currently 1.6 death in 100 000 live birth) however constantly is the first cause of maternal death (16%) (Deneux-Tharaux, C., Bonnet, M. P., & Tort, J.,2014). As well as in Malaysia, based on Statistic on causes of Death, primary PPH is the principal cause of maternal death in year 2019. It accounts for 17.5% of maternal death.

2.2 Causes of postpartum hemorrhage

There are variety causes of postpartum hemorrhage. Uterine atony is the most common cause of PPH, which contributes approximately 1 in 40 births in United States, which also responsible for almost 80% in PPH cases (Reale SC, Easter SR, Xu X, Bateman BT, Farber MK, 2020). Blood loss during delivery can be much greater than observed in uterine atony. Although, uterine atony is the most common cause of PPH, however it is not the most common factor that contributing to massive blood transfusion as it is often responsive to uterotonics drugs (Bateman BT, Berman MF, Riley LE, Leffert LR, 2010). Uterine atony may or may not be associated with retained tissue. Placenta disorders, retained products of conception and also uterine inversion may contribute to primary PPH, as they will inhibit efficacy of uterine contraction.

Trauma related bleeding also contributing to PPH, such as vaginal trauma or extended tear during caesarean section. It is however is the most common cause of PPH with blood loss more than 2500 mL, which is more common than uterine atony alone (Bell SF, Collis RE, Bailey C, James K, 2021). Less frequent causes of PPH is coagulopathy. It complicates about 1 in 500 births in the United States and contributes for less than 7% in cases of PPH (Reale SC, Easter SR, Xu X, Bateman BT, Farber MK, 2020). For women with inherited or acquired bleeding disorder, they are at risk for PPH due to coagulopathy or platelet dysfunction.

2.3 Shock index value

The shock index has been used widely as a better and earlier marker of compromise than conventional vital signs in non-pregnant populations (Allgower MBC. Shock index, 1967). It had been used specially in trauma (Paladino L, Subramanian RA, Nabors S, Sinert R, 2011) and sepsis (Rady MY, Nightingale P, Little RA, Edwards JD, 1992). Many studies conclude that normal SI range in healthy adults is 0.5-0.7 (Rady MY, Rivers EP, Martin GB, Smithline H, 1992), and it has been associated with increased risk of morbidity and mortality when the SI is more than 0.9 (Vandromme MJ, Griffin RL, Kerby JD, 2011). However, delay in recognition of hypovolemia may occur in pregnant women due to haemodynamic changes during pregnancy and postpartum (HL Nathan, El Ayadi, NL Hezelgrave, 2014). Therefore, threshold of shock index in obstetrics must be derived to validate for PPH. Hence, several studies have been conducted in order to determine the normal reference values during delivery and immediate postpartum period, as well as during PPH.

In a prospective study by Anderson Borovac Pinheiro et al in year 2018, they include 186 women who delivered vaginally and had blood loss less than 500mL. They calculated the blood loss by adding the blood volume collected in the drape and also weight of gauzes used. Shock index was measured every 5 minutes when women was in position for birth and every 15 minutes for 2 hours after the birth. Shock index values range 0.68-0.74 in puerperal period. It is observed with higher value within 20 minutes after delivery and lower values between 91-120 minutes after delivery. The normal values of SI that identified during this study can be used as a tool for risk stratification in women with potential to develop PPH.

Abigail Le Bas et al in year 2014 investigated a normal value of shock index in obstetrics population in retrospective case-control study. From this study, 50 case group (experienced normal blood loss less than 500 mL) and 50 control group (experience massive blood loss, minimum of 30% loss of blood volume during delivery) were analysed. They observed that in the case group, the mean obstetric shock index was 0.74 and no individual value in case group with shock index above 1.1. And they observed that in the control group, chance of getting blood transfusion is increased with obstetric shock index > 1.1. Thus, they proposed the normal obstetric shock index ranging 0.7-0.9.

In a study by Taylor et al in year 2016, they conclude a wider shock index range 0.46-1.07 within the first 24 hours after delivery. The study was conducted retrospectively in 8874 deliveries, which include both women that delivered vaginally and via caesarean section. They noted an increased shock index was observed among patients who delivered via caesarean section compared to vaginal birth. However, the blood loss was measured visually which is often inaccurate.

2.4 Conventional vital signs versus shock index

Several studies have analysed the effectiveness of shock index in PPH, in comparison with conventional vital signs such as heart rate, systolic blood pressure and diastolic blood pressure. In the studies conducted by Nathan et al in year 2014, systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), pulse pressure (PP) and shock index (SI) were measured within the first hour following postpartum haemorrhage, in 233 women that had blood loss more than 1500mL. Each of the parameters were used to predict the need for blood transfusion, haemoglobin level less than 7 g/dL, required invasive surgical procedures (haemostatic uterine suturing, uterine tear repair, uterine artery embolization, bilateral internal iliac arteries ligation, aortic artery clamping and hysterectomy) and admission to intensive care unit (ICU). From the study, SI and HR were significantly better predictors compare to all other vital signs in prediction of ICU admission as well as invasive surgical intervention. However, SI had the highest AUROC of 0.67 for blood transfusion, in comparison to HR. From this study, they concluded that SI is consistently useful predictors in all adverse outcomes.

Se Young Lee et al in year 2018 did a retrospective study on 118 patients that were referred to Korea University Medical Center, Ansar. In their study, they analysed a data for systolic blood pressure, diastolic blood pressure, heart rate and shock index at time of arrival. And they reviewed significant morbidities, such as massive blood transfusion (more than 10 units of red blood cells), invasive procedures (pelvic artery embolization, hemostatic suture with laparotomy either on the uterus or pelvic vessels, and hysterectomy) and admission to ICU that correlate with the measured parameters. For each these three adverse clinical outcomes, shock index was consistently had the highest AUROC value in comparison to systolic blood pressure, diastolic blood pressure and heart rate.

A prospective cohort study by Hannah et al in year 2013 in South Africa hospitals, was conducted in two groups; 283 women with PPH and 126 women with maternal sepsis. They compared shock index with conventional vital signs as a predictor of outcomes (admission to ICU, invasive procedures and requirement for blood transfusion). They conclude that risk of all outcomes increased in increasing of shock index in both groups.

In year 2014, Era Sumiko et al retrospectively analysed 80 emergency referral patients who had received blood transfusion during or after the delivery. They compared factors such as estimated blood loss, fibrinogen level, haemoglobin (Hb) concentration and shock index in determining the requirement of blood transfusion. They evaluate that shock index had significant positive correlation with amount of blood transfused. However, fibrinogen level showed a strongest correlation with amount of blood transfused. As shock index is calculated instantaneously, it is easier and useful to use in clinical setting compare to fibrinogen level, that cannot always be easily measured in all facilities.

C.H. Sohn et al in year 2018 did a retrospective study on 302 patients with primary postpartum haemorrhage in the emergency department of a tertiary referral centre in Korea between January 1, 2004 and December 31, 2015. Parameters such as systolic blood pressure, diastolic blood pressure, heart rate, shock index and blood lactate concentration test were performed within minutes of arriving at the emergency department. Requirement for massive blood transfusion (more than 10 units of packed cells) was the primary outcome of this study. From this study, they concluded that lactate concentration was independently associated with requirement of massive blood transfusion, as well as shock index in comparison with other parameters. Nevertheless, combining of lactate concentration and shock index will improve the predictive requirement for massive blood transfusion. Thus, this will to focus on early detection and intervention of PPH. However, like fibrinogen level, lactate concentration may not readily available in small district hospital or low income center.

2.5 Outcomes of PPH based on shock index

Abigail Le Bas et al in year 2014 investigated a normal value of shock index in obstetrics population in retrospective case-control study, 50 women with no PPH (control group) and 50 women with massive PPH (more than 30% loss of blood volume; case group). Shock index were calculated at 10 minutes and 30 minutes from onset of PPH. In control group, mean shock index value range 0.74-0.76. While in case group, mean shock index value range 0.90-0.91. And majority of women with shock index more than 1.1 at 10 minutes and 30 minutes required blood transfusion.

A retrospective cohort study by Chan HS et al in year 2013 involved 126 patients, which were further classifies into two groups; massive transfusion group (received more than 10 units of packed red blood cells within 24 hours of ED admission) and non-massive transfusion group (received less than 10 units od packed RBC). They found out that initial shock index was significantly higher in massive transfusion group than in non-massive transfusion group. They conclude that increased massive transfusion rate was observed in shock index more than 0.7. 66.7% women with shock index more than 1.3 or greater required massive transfusion.

A retrospective study by HL Nathan et al in year 2014, it was conducted in UK tertiary centre. 233 women with blood loss more than 1500 mL were included in the study. Shock and other conventional vital signs were measured within the first hour from onset of PPH. Each of measured parameters were correlate with clinical outcomes; blood transfusion requirement more than 4 units, invasive surgical procedures and admission to ICU. They suggested a shock index more or greater than 0.9 is the upper limit in immediately postpartum, whereas shock index more or greater than 1.7 indicates an urgent intervention.

3.0 STUDY JUSTIFICATION

There are only a few studies assessing the value of shock index in pregnancy populations. Some studies proposed that shock index in pregnant population is lower in comparison to non-pregnant population. Threshold of SI >0.9 is indicating the need for referral to higher level facility and SI >0.7 indicating the need of urgent intervention (HL Nathan, 2014). Very few studies were conducted to evaluate the shock index of primary PPH in women that delivered vaginally. Spinal anaesthesia that is given prior to caesarean section is known to induce hypotension. Thus patient will be preloaded with fluid before the procedure to prevent hypotension. This might effects the conventional vital signs and indirectly shock index as well in caesarean section complicated with primary PPH. For this reason, this study will only look at women who delivered vaginally with estimated blood loss more than 500 mL. However, there will discrepancy in those patients that received epidural intrapartum as they will be preloaded with fluid as well. Thus, we will analysed obstetric SI in patients that delivered vaginally with or without epidural.

Although shock index has been reported to be a useful adjunct in managing hypovolemic shock, but it was mainly and widely used in non-pregnant populations. It is rarely used in managing primary PPH especially in low resource setting especially in rural area. In rural area where majority of cases are attended by junior and inexperienced medical practitioners, this simple tool of diagnosis will help and guide in early recognition of PPH. Thus, an early intervention can be start and this will significantly reduce maternal morbidity and mortality.

4.0 RESEARCH QUESTION

What is the relationship between shock index and outcomes of primary postpartum haemorrhage?

5.0 OBJECTIVES OF THE STUDY

5.1 General Objective

To determine relationship between shock index and outcomes of primary postpartum haemorrhage.

5.2 Specific Objectives:

1. To determine proportion of blood transfusion in relation to shock index.
2. To determine proportion of surgical intervention in relation to shock index.
3. To determine proportion of ICU admission in relation to shock index.

6.0 METHODOLOGY

6.1 Study design, venue and duration

This is a retrospective cohort study which was conducted in the Obstetrics and Gynaecology Department, Hospital Sultan Ismail Johor Bahru. It is a tertiary hospital and the referral centre for district hospitals from Mersing and Kota Tinggi, with total deliveries of 10000 per year. This study was carried out for 5 years durations, from January 2015 till December 2020.

6.2 Reference population

All women who delivered at term, via vaginal delivery in Hospital Sultan Ismail, Johor Bahru with estimated blood loss of more than 500 mL.

6.3 Vulnerability

The subjects data will be reviewed retrospectively. Thus, these will not affect vulnerability.

6.4 Study participants

Study participants include all women who delivered at term via vaginal delivery with estimated blood loss of more than 500 mL, at Hospital Sultan Ismail Johor Bahru.

6.5 Sample size calculation

Sample size is calculated for all the factors to be studied. Using sample size calculator USM. Using single proportion formula.

$n = (Z/\Delta)^2\, p(1-p)$

$Z\alpha$= critical value for α, α =0.05 therefore $Z\alpha$ =1.96

Δ = precision = 0.05

	Prevalence	Corrected sample size	Total number sample (include 20% drop out)
1. Blood transfusion	17.5	222	278
2. Surgical intervention	5.1	75	94
3. ICU admission	5.1	75	92

Reference : Nathan et al (2014) Table 3

After considering 20% drop out, the biggest sample size is 278.

Therefore, the final sample size for this study is 278.

6.6 Ethics and consent

The conduct of this study was approved by the National Medical Research Review and by Human Research Ethical and Committee of HUSM. Letter of approval is attached in appendix.

6.7 Inclusion and exclusion criteria

6.7.1 Inclusion criteria

All pregnant women who delivered vaginally in Hospital Sultan Ismail, Johor Bahru with estimated blood loss of more than 500 mL.

6.7.2 Exclusion criteria

Exclusion criteria are as follow:

1) Preterm delivery
2) Maternal sepsis
3) Pregnant women with medical illness such as :
    - Heart diseases

- Hypertension
- Blood disorders
- Thyroid disease

6.8 Sampling method

Systematic sampling

- The patients will be included based on a systematic rule, such as all patient that delivered vaginally with blood loss of more than 500 mL.

6.9 Subject recruitment

All patients that delivered vaginally in Hospital Sultan Ismail, Johor Bahru from January 2015 till December 2020 with estimated blood loss of more than 500 mL was recruited and the recorded vital signs was taken.

6.10 Data collection method

This was a retrospective study. Data collection was started after approval of the research ethical board committee. All subjects that delivered in Hospital Sultan Ismail, Johor Bahru via vaginal delivery with blood loss of more than 500 mL was reviewed, from January 2015 till December 2020.

The information was collected from the patient's data in the Hospital Sultan Ismail Powerchart. Obstetrics shock index were taken at 15 minutes, 30 minutes , 1 hour and 2 hours from the onset primary PPH and the highest obstetric shock index will be used for analysis. The data necessary was then recorded into data collection sheets. The data was analysed and processed to obtain results.

6.11 Statistical analysis

All data in checklist will be collected in database and computed using Excel®. Then will be analysed using Statistical Package for the Social Sciences (IBM SPSS® version 27).

A descriptive analysis is used to summarize the demographic characteristics (Age, Parity, BMI, mode of delivery). The median value will be used when normal distribution is absent.

Descriptive statistic was used in this study to determine proportion of blood transfusion in relation to obstetric shock index, proportion of surgical intervention in relation to obstetric shock index and proportion of ICU admission in relation to shock index.

Mann-Whitney u test and independent t-test were used to determine relationship between obstetric shock index and outcome of primary postpartum haemorrhage; requirement of blood transfusion, surgical intervention and ICU admission.

6.12 Definition of Operational Term

i. Body mass index (BMI): BMI is the metric currently in use for defining anthropometric height/weight characteristics in adults and for classifying them into groups. The classification of BMI for this study was adapted from WH, that categorized into four groups; underweight (<18.5kg/m^2), normal weight (18.5-24.9 kg/m^2), overweight (25-29.9 kg/m^2) and obese (>30 kg/m^2).
ii. Gravida: number of pregnancies a woman has had regardless of the pregnancy outcomes.
iii. Maternal morbidity: medical complications in a woman caused by pregnancy, labour or delivery.