Blood Loss in Caesarean Section in Hospital Universiti Sains Malaysia (HUSM): Estimation by Surgeons and Anaesthetists In Comparison with Quantitative Measurement and Blood Parameters Assessments

by

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List of Abbreviation

ABL	Allowable Blood Loss
AFI	Amniotic Fluid Index
CF	Consent Form
CS	Caesarean Section
Delta Hb	Difference inTwo Haemoglobin Readings Taken at Different Timing
EBL	Estimated Blood Loss
EBV	Estimation of Blood Volume
GOT	General Operation Theatre
Hb	Haemoglobin
Hb(o)	Haemoglobin Level within 1 hour post Caesarean Section
Hb (p)	Preoperative Haemoglobin
Hct	Haemotocrit
HUSM	Hospital Universiti Sains Malaysia
IO	Input and Output
IUGR	Intrauterine Growth Restriction
MBL	Measured Blood Loss
MMC	Malaysian Medical Council
MOT	Maternal Operation Theatre
PIS	Patient/Participant Information Sheet
PPH	Posrpartum haemorrhage
SD	Standard Deviation
VD	Vaginal delivery
WHO	World Health Organization

Kehilangan Darah Semasa Pembedahan *Caesarean* di Hospital Universiti Sains Malaysia: Jangkaan Oleh Doktor Bedah Dan Doktor Bius Dengan Perbandingan Kepada Nilai Kuantitatif Dan Penilaian Keputusan Darah

Abstrak

Latar belakang: Kami telah membandingkan jangkaan visual kehilangan darah bagi Pembedahan *Caesarean* (CS) oleh doktor bedah dan doktor bius dengan nilaian kuantitatif beserta perkaitan dengan tahun pengalaman dan ketepatan jangkaan. Pola hemoglobin (Hb) selepas CS juga dikaji.

Metodologi: Sejumlah 134 pesakit yang menjalani CS menyertai kajian ini. Jangkaan visual diambil daripada doktor bedah dan bius seusai CS selesai. Darah di dalam bekas takungan darah dan barang-barang pakaibuang ditimbang dan ditolak berat kering untuk mendapatkan berat bersih. Takat Hb sebelum CS dan sejam serta 24 jam selepas CS diambil. Data yang tercatat dianalisa menggunakan kaedah Ujian Realibiliti, Ujian-T Tidak Berkait, Korelasi *Pearson* dan Regresi Linear Berbilang dengan mengambil nilai $P < 0.05$ sebagai signifikan.

Keputusan: Terdapat hubungkait yang kuat di antara jangkaan pendarahan pesakit CS oleh doktor bedah dan doktor bius dengan nilaian kuantitatif dengan nilai Koefisien Korelasi Dalam Kelas ($r = 0.828$ dan $r = 0.805$, $P < 0.001$). Pengalaman doktor bedah di dalam kelas 5 tahun ke bawah dan 6 tahun ke atas tidak signifikan dalam menentukan ketepatan jangkaan pendarahan CS, $P = 0.053$. Manakala, perbezaan pengalaman doktor bius di dalam kelas 5 tahun ke bawah dibandingkan dengan kelas 6 tahun ke atas adalah signifikan dalam menentukan ketepatan jangkaan pendarahan CS, $P = 0.038$. Terdapat korelasi negatif yang sederhana di antara peratusan kehilangan darah dengan Delta Hb selepas 1 jam, $P < 0.001$.

Peratusan kehilangan darah, kuantiti air intravena yang diberi semasa CS dan parut CS pesakit sebelum ini merupakan kayu ukur penting untuk meramal nilai Delta Hb selepas 1 jam CS.

Kesimpulan: Jangkaan kehilangan darah bagi CS oleh doktor bedah dan doktor bius berkaitrapat dengan nilaian kuantitatif. Penurunan nilai Hb seusai CS berkadaran dengan peratusan kehilangan darah. Ramalan Hb sejam dan 24 jam selepas CS berpotensi besar sebagai alat untuk membantu para doktor dalam merawat pesakit.

Kata kunci: Pembedahan *Caesarean*, jangkaan doktor bedah, jangkaan doktor bius, Delta Hb 1 jam selepas CS, peratusan kehilangan darah

Blood Loss in Caesarean Section in Hospital Universiti Sains Malaysia (HUSM): Estimation by Surgeons and Anaesthetists In Comparison with Quantitative Measurement and Blood Parameters Assessments

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Abstract

Background: We compared the visual estimation of blood loss for Caesarean section (CS) by surgeons and anaethetists and their accuracy with relation to years of experience against quantitative measurement. Haemoglobin (Hb) trend after CS were also studied.

Methods: 134 patients who underwent CS were included. Visual estimations were reported by surgeons and anaesthetists. The blood volume in collection bottle and disposable items were quantified. Hb levels pre-CS followed by 1 hour and 24 hours post CS were taken. Data were tested by Reliability Testing, Independent T-Test, Pearson's Correlation and Multiple Linear Regressions where $P < 0.05$ is considered significant.

Results: There were strong correlation between surgeon's and anaesthetist's estimations of blood loss and quantitative measurement with Intraclass Correlation Coefficient of $r = 0.828$

and r = 0.805, $P < 0.001$. Surgeons' accuracy in estimating blood loss has no significant difference in less and equal to 5 experience years against more than 6 experience years group, $P = 0.053$. Anaesthetists' accuracy in estimating blood loss has significant difference in less and equal to 5 experience years against more than 6 experience years group, $P = 0.038$. There was moderate negative correlation in between percentage blood loss and Delta Hb 1 hour post CS, $P < 0.001$. Percentage blood loss, intraoperative fluid administration and patient previous scars were strong predictors for Delta Hb 1 hour post CS with $P < 0.05$.

Conclusions: Estimation blood loss for CS by surgeons and anaesthetists in HUSM correlates with quantitative measurement. Drop in Hb post CS correlates with percentage blood loss. Prediction of Delta Hb 1 hour and 24 hours post CS can be a useful tool in helping doctors in managing patient.

Keywords: Caesarean section, surgeon's estimation, anaesthetist's estimation, Delta Hb post 1 hour CS, Percentage blood loss

2.1 Introduction

Bleeding is a major threat for postpartum mortality which is commonly due to uterine atony and in women age group of more than 40 years old (Jolly et al., 2000; Bateman et al., 2010). According to Walfish, Neuman and Wlody (2009), 25-30% of maternal mortality in United States is because of maternal haemorrhage. Knight et al., 2009 states that the trend for caesarean section has increased globally. However, in contrast, the assessment of the blood loss in caesarean section which is essential to determine the bleeding severity was found to be exaggerated or underestimated (Larsson et al., 2006).

Classifications of postpartum haemorrhage (PPH) mainly depend on the estimation of blood loss and may vary in developed countries (Knight et al., 2009; Bateman et al., 2010). United States and Canada defines postpartum haemorrhage as blood loss more than 500 millilitres (mls) in vaginal delivery (VD) and more than 1000 mls in Caesarean section (CS) whilst in Australia, PPH is blood loss more than 500 mls in VD and more than 750 mls in CS (Knight et al., 2009). Siva Achanna, K., 2011 notes, in Malaysia, PPH defines as any blood loss either from VD or CS of more than 500 mls in as in accordance to the World Health Organization (WHO) definition. Where else, 1000 mls of blood loss and above is labelled as severe PPH based on WHO definition.

Generalizing the blood loss in patient is unfair in terms of assessing the severity of blood loss. The definition of PPH needs to be revised to cater the blood volume loss of the mother which reflects the severity of blood loss (Knight et al., 2009). For example, the revision of definition of blood loss in CS by estimating the blood loss from haemoglobin level drop by 2 g/dL rather than generalizing to certain numbers i.e. 500mls or 1000 mls. The variance in weight and height may cause huge differences in the amount of blood volume in each patient. Therefore, patients with higher blood volume can withstand higher quantity of blood loss in CS in comparison to patients with lower blood volume i.e. smaller

weight and height.

The purpose of the study is to compare various estimation of blood loss in CS and to detect the most accurate and practical method of assessing blood loss in patient. Methods can be by visual estimation by attending surgeon and anesthetist, clinical assessment to ascertain signs of shock related to blood loss, mechanical measurement of blood and liquor from disposable and non-disposable items and blood parameters which include haemoglobin and haematocrit pre-CS and post-CS. Post CS blood sampling can vary from immediate within 1 hour and after 24 hours post CS (Larsson et al., 2006). The data will collected by random sampling over the period of study which in inclusive criteria and achieve target sample as calculated by statistical manner.

As conclusion, it is beneficial if the study can provide a new light to the method as assessing blood loss in caesarean. Hopefully, this study will provide a guide for health care practitioners in anticipating postpartum haemorrhage related to caesarean section.

2.2 STUDY PROTOCOL

2.2.1 BACKGROUND OF STUDY

Bleeding is a major threat for postpartum mortality which is commonly due to uterine atony and in women age group of more than 40 years old (Jolly et al., 2000; Bateman et al., 2010). According to Walfish, Neuman and Wlody (2009), 25-30% of maternal mortality in United States is because of maternal haemorrhage. Knight et al., 2009 states that the trend for caesarean section has increased globally. However, in contrast, the assessment of the blood loss in caesarean section which is essential to determine the bleeding severity was found to be exaggerated or underestimated (Larsson et al., 2006).

Classifications of postpartum hemorrhage (PPH) mainly depend on the estimation of

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The purpose of the study is to compare various estimation of blood loss in CS and to detect the most accurate method of assessing blood loss in patient. Method can be by visual estimation by attending surgeon and anesthetist, clinical assessment to ascertain signs of shock related to blood loss, mechanical measurement of blood and liquor from disposable and non-disposable items and blood parameters which include haemoglobin and haematocrit pre-CS and post-CS. Post CS blood sampling can vary from immediate within 1 hour and after 24 hours post CS (Larsson et al., 2006). The data will collected by random sampling over the period of study which in inclusive criteria and achieve target sample as calculated by statistical manner.

As conclusion, it is beneficial if the study can provide a new light to the method as assessing blood loss in caesarean. Hopefully, this study will provide a guide for health care practitioners in anticipating postpartum haemorrhage related to caesarean section.

2.2.2 PROBLEM STATEMENT

i) Estimation of blood loss in Caesarean section by surgeons or anaesthetists is non-evidential and mere speculative and maybe detrimental

ii) Quantitative and blood parameters measurements are not usually done to estimate the blood volume loss

iii) Post Caesarean section blood parameters pattern is not fully understood to determine the critical period in drop or increment of haemoglobin level

2.2.3 JUSTIFICATION OF THE STUDY

Based on the problems stated above, justifications of this study can be summarized as:

i) Visual estimation of blood loss is unreliable and should be less likely use as the cutting point for postpartum haemorrhage severity. Therefore, this study is to prove the visual estimation of blood loss is a speculative estimation (Knight et al., 2009)

ii) More practical measurement of blood loss can be done by mechanical measurement of blood loss and by blood paramaters. (Larsson et al., 2006). Alkaline hematin method for quantitative measurement of pack cells loss is not available in Malaysia. Alkaline hematin method is taken as a Gold Standard for pack cells loss estimation from disposable items and non-disposable items.

iii) Clinical assessment to determine severity of blood loss depends on the knowledge, experience and awareness of the attending health care practitioner and may cause delay of detection of blood loss severity thus intervention (Siva Achanna, K., 2011).

iv) Blood sampling pre and post Caesarean section study is a more objective assessment for pack cell loss. Sampling will take into account the level of haemoglobin which is crucial in determining the oxygen flux in the body (Stoelting, 2011).

v) Normal haemoglobin level can be vary immediately post operatively in comparison to after 24 hours of Caesarean section which can be altered due to delayed haematoma formation, loss of blood from lochia, auto-transfusion from contracting uterus and pack cells transfusion if given.

2.2.4 RESEARCH OBJECTIVES

The study research objectives are divided into general and specific objectives:

GENERAL OBJECTIVES

1. To assess the most appropriate and reliable method of assessing blood loss related to Caesarean section

SPECIFIC OBJECTIVES

1. To compare the accuracy of estimation of blood loss in Caesarean section by health care practitioners compared to quantitatively measured blood loss by mechanical and blood parameters by health care practitioners.
2. To compare the accuracy of estimation of blood loss in Caesarean section in comparison to the measured blood loss by years of experience.
3. To analyze the changes in the haematocrit level with relation to haemoglobin level in pre and post-Caesarean section and to compare estimated blood loss by anaesthetists and surgeons with quantitative measurement.

2.2.5 RESEARCH QUESTIONS

1. Are there any differences in visual estimation by doctors against the measured blood loss by blood parameters or mechanical measurement?
2. Do health care practitioners' years of experience give higher accuracy in estimation of blood loss in study samples?
3. Are there any associations in quantitatively measured blood loss in Caesarean section in comparison to measured haemoglobin and haematocrit readings?

2.2.6 RESEARCH NULL HYPOTHESIS (H_0)

i. There is no difference of estimation of blood loss for Caesarean section by visual estimation by doctors comparable to quantitatively measured blood loss.

ii. Experience of health care practitioners does not affect the accuracy of visual estimation of blood loss.

iii. Quantitatively measured blood loss in Caesarean section will not proportionate the haemoglobin and haematocrit readings.

2.2.7 BENEFITS OF THE STUDY

i. Better method of assessment for blood loss in Caesarean section can be recommended if any there are positive findings in the study.

ii. May propose a revision for current classification for postpartum haemorrhage (PPH)

2.2.8 LIMITATIONS OF THE STUDY

i. Not enough sample due to unable to obtain consent from patients due to refusal of blood takings
ii. This study can only be representative to Hospital Universiti Sains Malaysia (HUSM) only as it is not representing the people in Kelantan
iii. Level of education and socioeconomic background can limit the understanding of the importance of the study
iv. Untrained medical personnel in retrieving data can be overcome by proper training and briefing

2.2.9 RESEARCH METHODS AND METHODOLOGY

2.2.9.1 RESEARCH DESIGN

This is a descriptive study that will be conducted in the Maternal Operation Theatre and General Operation Theatre of Hospital Universiti Sains Malaysia (HUSM). Study period will be from April 2016 until October 2017. Reference population will be the all patients subjected to Caesarean section in HUSM. Source of population will be taken from patients who will undergo Caesarean section in the Maternal Operation Theatre and General Operation Theatre HUSM. Samples recruited will be pregnant lady who will undergo elective or emergency Caesarean section in the designated area. Source of sample for surgeons and anaesthetists involved in this study will be taken from the respective departments and must be consented by them. These doctors will be informed prior to the study involvement. This study will take around 18 months.

This research will be done in a single phase which involves data collection and thesis writing. Upon completion of the data collection, analysis of the data available will be done and compiled in a thesis. It is hoped at the end of this study, all the objectives of this research will be fulfilled.

2.2.9.2 SAMPLE SIZE CALCULATION

Objective 1:

In order to determine the sample needed for comparison of estimated, quantitative measured and calculated blood loss. Larsson et. al (2006) has standard deviation (SD) of 228 mililitres in visual estimation of blood loss and measured.

This study involves continuous response variable from independent control and experimental subjects with 1 control(s) per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 228. If the true difference in the experimental and control means is 114, we will need to study 64 experimental subjects and 64 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. Including 10 percent dropout rates, the number of sample will be 128 + (0.1)128 = 141 samples are required.

Objective 2:

No studies were found to relate years of experience of the visual estimation by surgeons or anaesthetists to measure accuracy of Caesarean section blood loss estimation.

Thus, for this objective the number of samples required will be at least 20 samples for each arm of study, making minimum of 40 samples per group of comparison. By comparing 3 different age groups, thus requiring 3 set of sample for each group namely Group A (less than 5 years of experience) and Group B (5 to 10 years of experience) To compare Group A vs Group B, minimal of 80 samples are required. By considering 10 percent dropout rates, thus, 88 samples are required to nullify the hypothesis.

Objective 3:

A study conducted by Ashraf Aly & Ramadani (2006), showed that there is average drop of haematocrit level by 4.5% with 1.13% standard deviation after Caesarean section. For a study of a continuous response variable from independent control and experimental subjects with 1 control(s) per experimental subject and if the true difference in the experimental and control means is 0.565, we will need to study 64 experimental subjects and 64 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. Including 10 percent dropout rates, the number of sample will be 128 + (0.1)128 = 141 samples are required.

By taking into consideration of all objectives, the highest sample number out of three objectives will be taken. Thus, for this study minimum 141 samples are needed including 10 percent dropout rates.

2.2.9.3 SAMPLING METHOD

For this research, random sampling will be used from the source population as mentioned before.

2.2.9.4 INCLUSION AND EXCLUSION CRITERIA

There will be two groups of sample that will be studied, first, the patients and second, the doctors which are the surgeons and the anaesthetists. Thus the criteria for inclusion, exclusion and withdrawal will be included as below:

I) PATIENTS' INCLUSION, EXCLUSION AND WITHDRAWAL CRITERIA

INCLUSION CRITERIA FOR PATIENTS

a) Women aged 18 to 50 years old
b) Any Caesarean section
c) Time taken for consent does not interfere with the timing of surgery and outcome of mother and the baby/babies
d) Able to give consent
e) Next of kin consent will be taken if the subject is legally unfit
f) Not diagnosed with any mental illnesses
g) Able to understand the consent in English Language or 'Bahasa Melayu'

EXCLUSION CRITERIA FOR PATIENTS

a) Caesarean hysterectomy

WITHDRAWAL CRITERIA FOR PATIENTS

a) Patient decided not to be the part of the study at any point of time during the study period

b) Patient refused to undergo any procedure necessary for the study at the stipulated time as per mentioned in the study design

II) DOCTORS' INCLUSION, EXCLUSION AND WITHDRAWAL CRITERIA

INCLUSION CRITERIA FOR DOCTORS

a) Must be a practicing and registered surgeon or anaesthetist under Malaysian Medical Council (MMC)
b) Involve directly in the operation either as a surgeon(s) or as an aneasthetist(s)
c) No restriction in the experience in respective field for both surgeons and anaesthetists and must be allowed by respective departments to perform surgery or anaesthesia
d) Operation involving Caesarean section only
e) Anaesthesia either general anaesthesia or regional is accepted (it will not affect the outcome of estimating the amount of blood loss but it may affect the amount of the blood loss)
f) Not diagnosed to have any mental illnesses that deem unfit or unstable to give consent or perform operation or anaesthesia
g) Able to understand English Language or 'Bahasa Melayu' for consent

EXCLUSION CRITERIA FOR DOCTORS

a) Caesarean hysterectomy

WITHDRAWAL CRITERIA FOR DOCTORS

a) The doctors involve in this study have the right to withdraw from this study at any point of time during the period of the study despite consent has been given. The intention to withdraw must be in a written form and given to the Principal Investigator.

2.2.9.5 DATA COLLECTION

Sample will be obtained from Maternal Operation Theatre (MOT) and General Operation Theatre (GOT) HUSM in stipulated time by means of universal sampling. Consent will be taken from sample that will undergo elective or emergency Caesarean section. The indication for Caesarean section depends on the surgeon's decision. For example, indication for elective cases are macrosomic baby at term gestation, Placenta Praevia, baby with Intrauterine Growth Restriction (IUGR), pregnant mother at term with two previous Caesarean sections or more and others. Example of indication for emergency Caesarean sections are pregnant mother in hypertensive crises, pregnant mother with pre-eclampsia, placental abruption, bleeding Placenta Praevia, fetal distress by evidence of cardiotocography or by meconium stained liquor, fetal bradycardia and others. Both qualified surgeon and anaesthetist has consented to be part of the study.

Then, once the patient is consented for operation and patient fits into the inclusion criteria and absence of the exclusion criteria, she will be enrolled in the study after consent is obtained from the patient or by the legal lawful representative. The Principal Investigator (PI) will be responsible for the well-being of sample involved in this study and will be well attended if any questions arose. The boundaries and responsibilities of the PI towards the sample and vice versa are well mentioned in the Patient/Participation Information Sheet and Consent Form (PIS and CF) as attached in the Appendix C.

Then, the Estimation of blood volume (EBV) in mililitres will be done by using formula from Stafford et al. (2008) as below:

EBV = 0.75 x {[Maternal Height (inches) x 50] + [Maternal weight (pound) x 25]}

Converted to centimetre (cm) and kilogram (kg):

EBV = 0.75 x {[Maternal Height (cm) x 19.69] + [Maternal weight (kg) x 55.08]}

Hence, latest weight taken from patient pre-operatively will be used to estimate EBV.

In MOT or GOT, blood sample before Caesarean section for haemoglobin (Hb) and haematocrit (Hct) level will be drawn from patient and labelled as 'pre-CS or Sample A. This blood will be processed by in the Haematology Laboratory Hospital Universiti Sains Malaysia (HUSM) for Hb and Hct level by utilizing XE5000 series machine which is available in HUSM. During the operation, anaesthetists and surgeon will communicate each other to update the patient's condition and visual blood loss estimation.

Upon the rupture of placental membrane, fluid suctioned into the collection bottle will be marked and the liquor amount will be estimated and deducted later on. This will also be applied for fluid used in peritoneal washing. All the non-disposables and disposables items which have been premeasured at dry weight will be mechanically weighed by Seca™ weighing scale Model. 232, Made in Germany with Declaration of Conformity (please refer Appendix A) at the end of Caesarean section to include the amount of fluid loss in total which include liquor. Amount of estimated liquor will be recorded and compared.

One surgeon and one anaesthetist involved in the CS will provide their visual estimation of blood loss. Their years of experience in respected field will be categorized according to 5 years and below and 6 years and above. Sample B or 'post-CS' haemoglobin and haematocrit level will be taken before patient is discharged to the ward from OT within

1 hour post CS. Proper fluid input and output (IO) charting will be done noting the amount and types of fluid has been given or blood transfusion if given with its reason as well as the urine output or bowel output if any.

In the ward after 24 hours post CS another haemoglobin and haematocrit level will be taken and labelled as 'Sample C'. IO chart will noted and any blood transfusion given will be documented and their reasons of giving the blood. The Data Collection Form (see Appendix B) then will be collected and analyzed with complete level of Sample A, Sample B and Sample C. Time of blood sampling will be precisely written in comparison to CS done.

Expected haemoglobin level is calculated by using revised formula from Arria & Rodrigues-Morales (2011). Previous estimation of haemoglobin is taken as:

$$Hb = Hct/3$$

After a study conducted by Arria & Rodrigues-Morales (2011), in 6004 individuals living in coastal population of Venezuela in 2011 the mean estimated Hb by using previous formula shown to be overestimated. Thus, proposing a new formula of:

$$Hb = Hct/3.135 + 0.257$$

Khan & Chohan (2006) produced formula for calculated Hb as below,

$$\text{Calculated Hb} = \frac{\text{Hb (p)}}{\text{Total Hb}} \times [\text{EBL} - (\text{EBL} \times \frac{\text{Hb (p)}}{100}]$$

Hb (p): Preoperative Hb

Total Hb: $\frac{\text{Hb (p)}}{100}$ x patients blood volume (70 ml kg^{-1})

EBL: Estimated blood loss

Patient's blood volume will be calculated by using Stafford et. al (2008) as mentioned above.

By converting this formula, since post operative Hb will be known thus substituting the calculated Hb to post operative Hb i.e Hb (o), the EBL will be calculated as:

$$EBL = [Hb\ (o)/Hb\ (p) \times Total\ Hb]/[1/(1 - Hb\ (p)/100)]$$

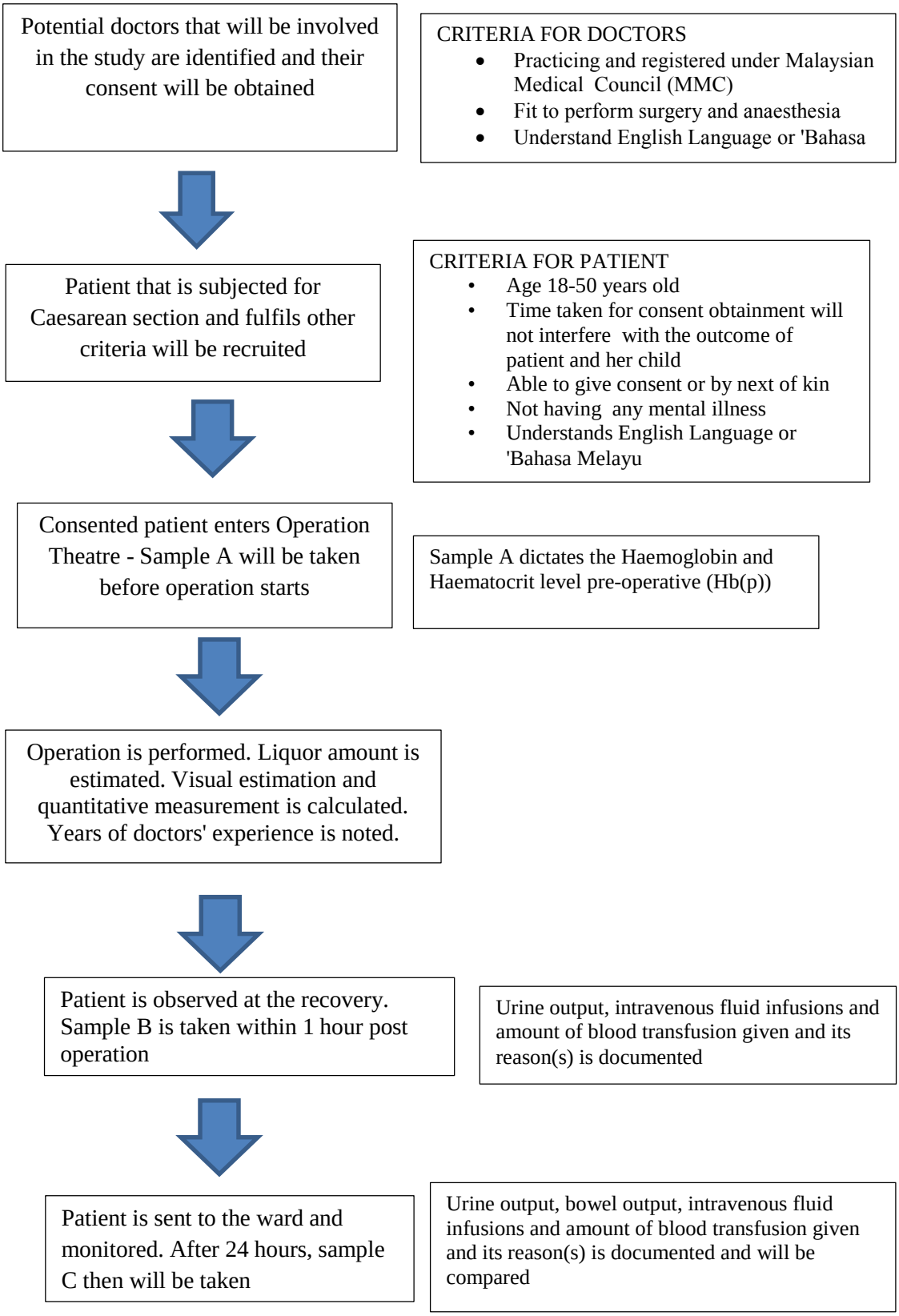
*Hb (o) is Hb within 1 hour post caesarean section i.e. Sample B.

To make it more accurate, Hb (o) level will be matched towards Hb (p) by matching the haemotocrit value pre and post caesarean section by using Arria & Rodrigues-Morales (2011) formula to eliminate influence of intravenous crystalloid or colloid infusions.

With assumption of at 24 hours of CS the blood volume will be normalized and comparable to baseline Hct, the deficit in Hb can be estimated and blood volume loss as well can be calculated giving the EBL within 24 hours. The value of sample C will be compared to value of sample B and determine their accuracy in comparing to the weighed blood loss as the reference value.

Thus, the visual estimation done by surgeons and anaesthetists will be documented and compared to the quantitative measurement by weighing scale and deduction as well as the calculated blood loss by using formula through Microsoft Excel 2015. The data collected will be then undergoes various statistical analyses by using IBM SPSS Statistics 22.

2.2.10 STUDY DESIGN FLOW CHART



Completed Data Collection Form (please refer to Appendix B) then will be completed and submitted to the Principal Investigator and analyzed. Blood loss estimation

by the blood parameters will be using an equation derived from Khan & Chohan (2006) Formula.

$$EBL = [Hb(o)/Hb(p) \times Total\ Hb]/[1/(1 - Hb(p)/100)]$$

Abbreviations:

EBL = Estimated blood loss

Hb(p) = Haemoglobin before operation

Hb(o) = Heamoglobin 1 hour after operation

Hb = Haemoglobin

2.2.11 INTENDED STATISTICAL ANALYSIS (ISA)

Objective	ISA
1. To compare the accuracy in general of estimation of blood loss in Caesarean section compared to measured blood loss by mechanical and blood parameters by health care practitioners	Intraclass Correlation Coefficient
2. To compare the years of experience of health care practitioners with the accuracy of estimation of blood loss in Caesarean section in comparison to the measured blood loss	Independent T-test
3. To analyze the changes in the haematocrit level with relation to haemoglobin level in pre and post-Caesarean section and compare with the blood loss via visual and quantitative measurement.	Pearson Correlation, Paired T-test and Multiple Linear Regression

2.2.12 EXPECTED RESULT

Result can be expected as below:

1. Visual estimation by doctors can be exaggerated or underestimated comparable to measured parameters and in unreliable
2. Doctors years of experience is little of significance in estimating blood loss
3. Measured blood loss mechanically can be different to the measured blood paramaters due to difficulty is estimating the liquor volume
4. Blood paramaters are more accurate and more acceptable for managing postpartum haemorrhage (PPH)

2.2.13 RESEARCH MILESTONE IN GANTT CHART AND FLOW CHART

2.2.13.1 GANNT CHART

BLOOD LOSS IN CAESAREAN SECTION IN HOSPITAL UNIVERSITI SAINS MALAYSIA (HUSM): ESTIMATION BY SURGEONS AND ANAESTHETISTS IN COMPARISON WITH QUANTITATIVE MEASUREMENT

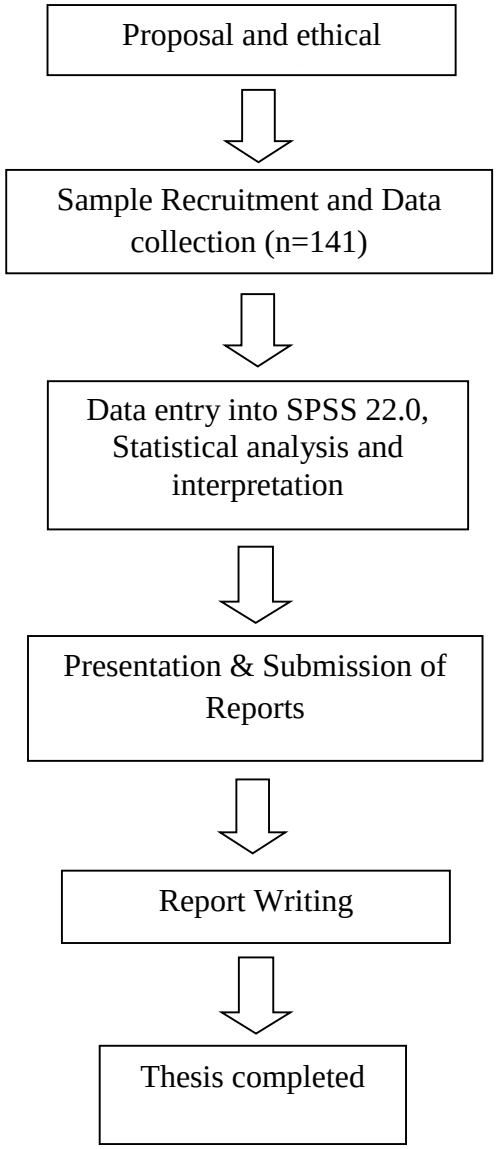
PROJECT ACTIVITIES	2016												2017											
Research Activities	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
Patient / Subjects Recruitment				→	→	→	→	→	→	→	→	→	→	→	→									
Data Collection				→	→	→	→	→	→	→	→	→	→	→	→									
Data Analysis / Interpretation																→	→	→						
Presentation & Submission of Reports																	→	→	→					
Report Writing																			→	→	→			
Project Completed																					→			
Submission of Research Papers																					→	→		

Milestone of Research Activities:

1. End of March 2017 : Completion of Data Collection
2. April 2017 : Data Analysis
3. May 2017: Preparation of Research Presentation
4. September 2017 : Report submission

2.2.13.2 GENERAL FLOW CHART

Flow chart



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   https://www.researchgate.net/publication/51093741_Differences_between_observed_and_estimated_by_hematocrit_hemoglobin_and_its_relevance_in_the_diagnosis_of_anemia_among_coastal_population_in_Venezuela_analysis_of_the_second_national_study_of_human_growth_and_development_%28SENACREDH%29

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APPENDIX A

declaration of conformity

seca

We, the manufacturer, declare in sole responsibility that the products mentioned below are in conformity with the respective regulations of the following directives.

Category	Measuring system for paediatrics					
Products	207	210	211	212	232	233
Classification medical device	Class I with measuring function					
Conformity assessment procedure for medical	In accordance with Annex VI of the Medical Devices Directive 93/42/EEC					

Directive:

93/42/EEC Directive concerning medical devices

Manufacturer:
seca gmbh & co. kg
Hammer Steindamm 9-25
22089 Hamburg, Germany

Made in Germany

Notified Body:
93/42/EEC:
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Munich, Germany

CE 0123

This declaration of conformity is valid from the date of signature until a revised declaration of conformity is issued due to modification of the above-mentioned products.

Hamburg, 17 / 10 / 2014

Frederik Vogel
CEO Development & Manufacturing