A 5-YEAR REVIEW OF STILLBIRTHS AND MATERNAL OBESITY IN HOSPITAL SULTANAH BAHIYAH ALOR SETAR KEDAH
(RETROSPECTIVE STUDY 2011-2015)

By

DR SITI SARAH BINTI AHMAD

Dissertation Submitted In Partial Fulfillment Of The Requirement For The Degree of Master Of Medicine (Obstetrics & Gynecology)

SCHOOL OF MEDICAL SCIENCES
UNIVERSITI SAINS MALAYSIA

2018

1.0 PRELIMINARIES

1.1 TABLE OF CONTENTS 1-3

1.2 ACKNOWLEDGEMENT 4

1.3 ABSTRAK 5-7

1.4 ABSTRACT 8-10

2.0 INTRODUCTION 11-12

2.1 Literature review 13-17

2.2 Study Justification 18

3.0 OBJECTIVES 19

3.1 General objectives 19

3.2 Specific objectives 19

4.0 RESEARCH METHODOLOGY 20-29

5.0 MANUSCRIPT 30

5.1 ABSTRACTS 30-32

5.2 INTRODUCTION 33-34

5.3 MATERIALS AND METHODOLOGY 35-36

5.4 RESULTS 37

5.4.1 DESCRIPTIVE STATISTIC (SAMPLE COLLECTION-FETUS) 37

5.4.1.1 Distribution of fetal weight during delivery 37-38

5.4.2 DESCRIPTIVE STATISTIC

(SAMPLE COLLECTION-MATERNAL) 39

5.4.2.1 Distribution of Patients age 39-40

5.4.2.2 Distribution of Ethnicity 41

5.4.2.3 Distribution of Parity 42

5.4.2.4 Distribution of Patient's BMI 43

5.4.2.5 Distribution of Patient's comorbidities 44-47

5.4.2.6 Distribution of Obstetric history 48

5.4.3 PROPORTION OF STILLBIRTH AND OBESITY AMONG

PREGNANT POPULATION IN HOSPITAL SULTANAH BAHIYAH 49

5.4.3.1 Descriptive statistic for obesity status 49

5.4.3.2 Descriptive statistic for obesity status according to age group 50

5.4.3.3 Descriptive statistic for obesity status according to ethnicity 51

5.4.3.4 Descriptive statistic for obesity status according to parity 51

5.4.4 RISK FACTORS THAT ASSOCIATED WITH STILLBIRTH

AMONG OBESITY MOTHER IN HOSPITAL SULTANAH BAHIYAH 52

5.4.4.1 Data Exploration and Cleaning 52-53

5.4.4.2 Simple Logistic Regression 54-55

5.4.4.3 Multiple Logistic Regression 56

5.4.4.4 Multicollinearity & Interaction 57

5.4.4.5 Checking Assumptions 58

5.4.4.6 Interpretation & Presentation 59-60

5.5 DISCUSSION 61-67

5.6 CONCLUSION 68

6.0 REFERENCES 69-73

7.0 TABLES AND FIGURES 74-76

8.0 APPENDICES 77

8.1 The Medical Journal of Malaysia (MJM) Format 77-88

8.2 Data Collection Sheet 89

8.3 Ethical Approval Letters 90

1.2 ACKNOWLEDGEMENT

All praises to Allah, the most merciful and beneficial and peace be upon our best teacher, Prophet Muhammad S.A.W.

I would like to express my heartiest gratitude and appreciation to my supervisor Dr Fauziah Jummaat, Lecturer and Specialist in the Department of Obstetric and Gynecology, Hospital University Sains Malaysia for her the kind assistance, encouragement and guidance to make this dissertation possible.

I would also like to extend my thank you to my supervisor in Department of Obstetrics and Gynaecology Hospital Sultanah Bahiyah Alor Setar, Dato' Dr Mohd Rushdan Md Noor (Senior Consultant Obstetrics and Gynaecologist and Head of Department Obstetrics and Gynaecologist Hospital Sultanah Bahiyah),all lecturers in HUSM, staff in O&G department and my fellow colleagues for their support in this study and for all the help in contributing to the dissertation.

Last but not least my special thanks to my family especially my parents for their prayers, sacrifice and support throughout these years.

1.3 ABSTRAK

A 5 YEARS REVIEW OF STILLBIRTH AND MATERNAL OBESITY IN HOSPITAL SULTANAH BAHIYAH ALOR SETAR (RETROSPECTIVE STUDY 2011-2015)

A Siti Sarah[1], J Fauziah[2], MN Rushdan[1]

Jabatan Obstetrik Dan Ginekologi Hospital Sultanah Bahiyah Alor Setar, Jabatan Obstetrik Dan Ginekologi, Hospital Universiti Sains Malaysia

PENGENALAN: Kelahiran mati menyumbang sebahagian besar daripada semua jumlah kematian perinatal. Definisi kelahiran mati adalah pelbagai mengikut tempat. WHO mentakrifkan kelahiran mati sebagai kelahiran bayi pada atau selepas 28 minggu kehamilan yang meninggal sebelum atau semasa proses kelahiran. Kadar obesiti meningkat di seluruh dunia dan mempunyai banyak implikasi terhadap kehamilan dan bayi dalam kandungan. WHO menggunakan indeks jisim badan (BMI) (berat (kg) / ketinggian (m) 2) untuk menentukan berat badan berlebihan dan obesiti. Berat badan berlebihan ditakrifkan sebagai BMI sebanyak 25 atau lebih. Obesiti boleh dibahagikan kepada 3 kategori; BMI 30.0-34.9 kelas 1 obesiti, BMI 35.0-39.9 kelas 2 obesiti, BMI 40.0 dan lebih kelas 3 atau morbid obesiti.

OBJEKTIF: Untuk menentukan perkiraan kelahiran mati di kalangan ibu-ibu obesiti, untuk mengkaji insiden obesiti pada populasi hamil yang mengalami kelahiran mati di Hospital Sultanah Bahiyah Alor Setar dan untuk menentukan risiko dan hubungan kelahiran mati dengan ibu mengandung yang obese.

KAEDAH KAJIAN: Kajian retrospektif ini dijalankan di Unit Obstetrik dan Ginekologi, Hospital Sultanah Bahiyah Alor Setar selama 5 tahun (Januari 2011 - Disember 2015) yang melibatkan 350 wanita hamil yang melahirkan bayi (kelahiran mati) pada usia 22 minggu atau lebih dengan kelahiran berat lebih daripada 500gm dan memenuhi kriteria kemasukan dan pengecualian.

KEPUTUSAN: Purata berat janin semasa kelahiran adalah 1630.00gm dengan median "interquartile range" (IQR ialah 1605.00). Manakala umur min ibu semasa "booking" adalah 30 tahun (SD: 6.12). Mereka adalah dari kumpulan umur 20-30 tahun (51.2%), diikuti oleh 31-40 tahun (39.4%). 331 pesakit daripada 350 (94.6%) adalah Melayu, 4.0% adalah cina, dan 1.4% adalah orang India. 65.4% daripada mereka adalah multipara dan 34.6% adalah primipara. 42 daripada 350 pesakit (12%) yang mengalami kelahiran mati mempunyai BMI> 30mg / m2 semasa "booking" dan dibahagikan kepada kelas obesiti 1,22 pesakit (6.3%), kelas obesiti 2, 14 pesakit (4.0%) dan kelas obesiti 3 , 6 pesakit (1.7%) . Hanya 5 pesakit (1.4%) yang kurang berat badan manakala 16% daripadanya adalah berat badan berlebihan (BMI> 25mg / m2). Di kalangan wanita obes, mereka adalah dalam kumpulan umur 31-40 tahun iaitu 6.6%, diikuti 3.1% dari kumpulan umur 21-30 tahun dan 2% daripada mereka berusia lebih daripada 41 tahun. Kita boleh membuat kesimpulan bahawa kelaziman kadar obesiti meningkat mengikut usia pesakit. Insidens obesiti lebih tinggi di kalangan multipara (9.1%) jika dibandingkan dengan primipara (2.9%).

327 daripada 350 orang pesakit (93.4%) tidak mempunyai tekanan darah tinggi sebelum atau semasa kehamilan. 4.6% (16) mempunyai hipertensi ketika hamil

manakala 1.4% (5) mempunyai pra hipertensi yang sedia ada. 18 pesakit (6.0%) daripada mereka mempunyai diabetes mellitus gestational dan 5 (1.4%) pesakit diketahui mempunyai diabetes mellitus sebelum hamil.

Insiden hipertensi sebelum mengandung ("essential hypertension") dalam kumpulan wanita obes adalah 0.6% dan 0.9% adalah antara pesakit yang tidak obes . Sementara itu, 0.9% pesakit obes mempunyai hipertensi semasa kehamilan ("gestational hypertension") dan 3.7% adalah pesakit yang tidak obes Insiden gestational diabetes mellitus di kalangan obes adalah 0.6% dan 5.4% pesakit tidak obes.Faktor risiko yang berkaitan dengan kelahiran mati di kalangan ibu obes adalah berkaitan dengan usia ibu. Berdasarkan usia ibu, dengan peningkatan usia 1 tahun akan mempunyai kemungkinan 13% lebih tinggi daripada mengalami kelahiran mati (95% CI 1.07, 1.19, p <0.001) apabila disesuaikan untuk penyakit auto-imun. Pesakit yang pra kehamilan mempunyai penyakit auto-imun akan mempunyai risiko 17% lebih tinggi untuk mendapatkan kelahiran mati (95% CI 2.89, 10.03, p = 0.002) apabila disesuaikan untuk umur pesakit.

KESIMPULAN: Obesiti ibu dikaitkan dengan peningkatan risiko dan komplikasi ibu dan neonatal, oleh itu pengesanan awal dan pengurusan segera adalah penting untuk mengatasi komplikasi maternal dan neonatal.

Keywords: BMI, obesity, stillbirth

(484 path perkataan)

1.4 ABSTRACTS

A 5 YEARS REVIEW OF STILLBIRTH AND MATERNAL OBESITY IN HOSPITAL SULTANAH BAHIYAH ALOR SETAR (RETROSPECTIVE STUDY 2011-2015)

A Siti Sarah[1], J Fauziah[2], MN Rushdan[1]

Obstetric and Gynaecology Department Hospital Sultanah Bahiyah Alor Setar, Department of Obstetric and Gynaecology, School of Medical Sciences, University Sains Malaysia.

INTRODUCTION: Stillbirth account for a large part of all perinatal death. It has various definition across the country and region. The WHO defines stillbirth as the birth of baby at or after 28 weeks who died before or during labour and birth. The prevalence of obesity is increasing worldwide and had many implications on pregnancy and perinatal outcome.WHO uses body mass index (BMI) (weight(kg)/height(m)2) to define overweight and obesity. Overweight is defined as a BMI of 25 or more. Obesity can be divided into 3 category; BMI of 30.0-34.9 class 1 obesity, BMI 35.0-39.9 class 2 obesity, BMI 40.0 and over class 3 or morbid obesity.

OBJECTIVES: To determine the proportion of stillbirth among obesity mothers, to establish and look for the incidence of obesity among mother who experience stillbirth in Hospital Sultanah Bahiyah Alor Setar and to determine the risk and association of stillbirth among obese mother.

METHODOLGY: A retrospective study was conducted in the Obstetrics and Gynaecology Unit, Hospital Sultanah Bahiyah Alor Setar for a period of 5 years (January 2011- December 2015) involving 350 pregnant women who delivered singleton pregnancy (stillbirth) at 22 weeks of gestation or more with birth weight more than 500gm and fulfilled the inclusion and exclusion criteria.

RESULTS: The overall mean fetal weight during delivery is 1630.00gm with median interquartile range (IQR is 1605.00). The mean age of mother during booking is 30 years old (SD: 6.12). They were at the age group of 20-30 years old (51.2%), followed by 31-40 years old (39.4%). 331 patient out of 350 (94.6%) is Malay, then 4.0% is chinese, and 1.4% is Indian. Majority of them 65.4% is multipara and 34.6% is primipara. 42 out of 350 patient (12%) who experience stillbirth is having BMI > 30mg/ m2 during booking which further divided to obesity class 1,22 patients (6.3%) , obesity class 2 , 14 patients (4.0%) and obesity class 3, 6 patient (1.7%) respectively. Only 5 patients (1.4%) is underweight while 16% of them is overweight (BMI >25mg/m2). Among obese women 6.6% of them in the age group of 31-40 years old , followed by 3.1% from age group of 21-30 years old and 2% of them is more than 41 years old. We can conclude that the prevalence of obesity is increase according to the age of patient . The occurrence of obesity is higher among multipara (9.1%) if compared to primipara (2.9%).

327 out of 350 patients (93.4%) didn't have hypertension prior or during pregnancy. 4.6% (16) have gestational hypertension, while 1.4% (5) who have pre existing hypertension. 18 patient (6.0%) of them having gestational diabetes mellitus and 5 (1.4%) of patient is known to have diabetes mellitus prior to pregnancy.The incidence of essential hypertension in obese group was 0.6% and 0.9% is among non obese patient. While 3.7% of non obese patient suffered from gestational hypertension. Only 0.9% of obese patients were affected. The incidence of gestational diabetes mellitus among obese is 0.6% and 5.4% of non obese patient.

Risk factors that associated with stillbirth among obese mother is related to maternal age. Based on maternal age, mother with 1-year increase in age will have 13% higher odds of having stillbirth (95% CI 1.07, 1.19, $p<0.001$) when adjusted for auto-immune disease. Those patient who pre pregnancy is having auto-immune disease will have 17% higher odds of having stillbirth (95% CI 2.89, 10.03, $p=0.002$) when adjusted for patients' age.

CONCLUSION: Maternal obesity is associated with increased risks of both maternal and neonatal complications, thus early recognition and prompt management is essential in order to improve maternal and neonatal outcome.

Keywords: BMI, obesity, stillbirth

(514 word)

2.0 INTRODUCTION

STILLBIRTH

Stillbirth account for a large part of all perinatal death. It has various definition across the country and region. In the UK, stillbirth is defined as baby of >/ 24 weeks of gestation delivered with no sign of life. In United States, the gestational age threshold for stillbirth is lower, >/20 weeks if the gestation age is known or birth weight >350gm if the gestational age is unknown. In Australia, stillbirth is applied to fatal death after 20 weeks of gestation or if the baby weighs more than 400gm. The WHO defines stillbirth as the birth of baby at or after 28 weeks , who died before or during labour and birth.

The aetiology of stillbirth include fetal causes such as chromosomal abnormalities which account for 30-60% of early fetal demise, 7% of foetuses with chromosomal abnormalities survive till term. While fetal structural abnormalities are found in 35% of fatal death commonly in renal and cardiac abnormality. Maternal association for stillbirth include obesity, smoking and medical illness such as endocrine disorder, renal, cardiac and haematological disorder. Pregnancy which complicated with diabetes are associated with a 5 times greater stillbirth rate if compared to uncomplicated pregnancies.

Infection accounts for 3% of stillbirths in UK which is preventable. Infection include ascending bacterial infection, viruses or parasites. Placenta abnormalities also account for 12% of stillbirths involves marginal insertion and velamentous insertion.

OBESITY

The prevalence of obesity is increasing worldwide and the global burden of overweight and obesity is estimated at more than 1.1 billion. WHO uses body mass index (BMI) (weight(kg)/height(m)2) to define overweight and obesity. Overweight is defined as a BMI of 25 or more. Obesity can be divided into 3 category; BMI of 30.0-34.9 class 1 obesity, BMI 35.0-39.9 class 2 obesity, BMI 40.0 and over class 3 or morbid obesity.While WHO classification of BMI for Asian population defined as overweight when BMI is more than 23, pre obese BMI: 23.0-27.4, Obese I: BMI of 27.5 – 34.9, Obese II: BMI of 35.0-39.9 and Obese III when BMI 40 and above [28].

The implications of obesity on pregnancy outcome varies such as miscarriage. The mechanism by which obesity increased risk of miscarriage is unclear. Others antenatal complication which may arise from obesity is gestational diabetes, pre eclampsia and thromboembolism. Obesity is a known risk factors for a number of fatal risk including prematurity, stillbirth, congenital anomalies, macrosomia and intrauterine fetal growth restriction.

2.1 LITERATURE REVIEW

Obesity is a major medical problem and is becoming more prevalent among women in reproductive age.Its continues to be a global health epidemic affecting nearly 300 million women worldwide [1] in which > 30% of women of reproductive age (aged 20-39 years) is obese and > 55% are overweight [2]. Obesity is considered by the World Health Organisation to be a disease and is defined as a condition of excess body fat to a degree where it causes impairment to the health of an individual.

The rate of obesity is increasing worldwide, in both economically rich and poor countries. In 2005, it was estimated that 23% of the adult population was overweight [3]. In Malaysia, the National Health and Morbidity Survey 1996 reported that in adult males, 15.1% were overweight and 2.9% obese while in adult females, 17.9% were overweight and 5.7% obese [4].In addition to the increased prevalence of obesity in the general population , the proportion of pregnant women who are obese is rising. A retrospective study of over 619 000 births from 34 UK maternity units determined that first trimester maternal obesity significantly increased over time and had more than doubled from 7.6% to 15.6% in 19 years [3].

Between 1990 and 2002/2004, obesity (BMI >30) in Scottish pregnant women double from 9.4% to 18.9% and women were 60% to be overweight or obese at antenatal booking [5].Data from the United States show a similar trend with maternal weight at booking increasing by 20% between 1980 and 1999 [6].Obesity in pregnant women is associated with a number of issues including recurrent miscarriage, increased risk of gestational diabetes, impaired fetal growth and poor obstetric outcome [3].

A retrospective study done among chinese women in Hong Kong between 1995 and 2005 showed 15.8% women had BMI >/25 kg/m2 at first visit, however if WHO's cutoff for Asian (BMI >/23 kg/m2) is used, the prevalence increase to 31.7%.[24]

Stillbirth is one of the important adverse pregnancy outcomes that has been used as a health indicator for the measurement of the health status of a country especially for its obstetric care management. The stillbirth rate fluctuated between 4.8 and 5.2 per 1000 total births from 2003-2006 [7]. Stillbirth rate in Malaysia in 2010 is 4.6 per 1000 birth [8].

In 2009, 2.6 million stillbirths were reported worldwide[9]. A number of risk factors for stillbirths have been identified, which include fetal abnormalities, intrauterine growth restriction, abruptio placenta, infection, older maternal age, and smoking during pregnancy [10], yet the cause of almost one half of all stillbirths are unknown [11].The association of an increased BMI with a higher stillbirth rate has been debated regularly

over the last two decades. A study published in 2014, suggest that 20% of stillbirths are associated with maternal obesity [12].

Obesity is a significant yet modifiable risk factor for stillbirth. A systematic review of observational studies found that mother who were overweight (adjusted odds ratio AOR 1.2. (95% CI 1.09-1.38) for BMI 25-30kg/m2) or obese (aOR 1.6 (95% CI 1.35-1.95) for BMI >30kg/m2) were at greater risk of stillbirth than those with a normal BMI [13].

A systematic review published in 2014 revealed that women with BMI of 40 were at twice the risk of stillbirth compare to women with a BMI of 20 (relative risk 2.19 (2.03-2.36) [14].

Large observational studies agree that overweight and obese mother are 40% more at risk of stillbirth [15]. A study in Aberdeen found that stillbirth was more common in obese [16] while a large cohort study in England reported fetal death to be two to three times more common in obese, but not overweight women [17].

The relationship between maternal BMI and this severe adverse outcome of pregnancy and delivery was first observed in 1998 when Cnattingius et al.(1998) stated in the Swedish Medical Birth Register that higher maternal BMI increase the risk of late fetal death [18]. These results were further confirmed and extrapolated to stillbirth, perinatal and infant death in the Danish Birth Cohort, which included 54,505 pregnant women [19]. In this study, it concluded that the risk of stillbirth increased 2 to 5 fold in obese pregnant women as compared with pregnant women with a normal BMI [20].

Aune et al. (2014) analysed 38 cohort studies (44 publications) and demonstrated that even a modest increase in BMI (overweight) was associated with an increased risk of stillbirth and other adverse outcomes during delivery: the RR per 5-unit increase in maternal BMI was 1.24 (CI, 1.18-1.30) [14]. In a most comprehensive population based analysis encompassing 134,527 obese women, Salihu et al. (2007) found that overall, obese mother were approximately 40% more likely to experience stillbirth than no obese women (adjusted HR 1.4; 95% CI 1.3-1.5). The risk for stillbirth increase in a dose dependent fashion with increasing BMI: class I, HR 1.3(95% CI 1.2-1.4); class II HR 1.4(95% CI 1.3-1.6); and class III HR 1.9(95% CI 1.6-2.1; *p* for trend < 0.01) [15].

A meta-analysis by Chu and colleagues published in American Journal Obstetrics &gynaecology in 2007 estimated the odds for a stillbirth were 1.47 (95 per cent CI 1.08–1.94) and 2.07 (95 per cent CI 1.59–2.74) higher in overweight (BMI 25–30) and obese (BMI >30) women, respectively, compared with normal weight (BMI 20–25) controls, again after allowing for maternal medical conditions during pregnancy. More recently, examining the obese group in more detail and breaking the BMI> 30 group into Class I (BMI 30–35), Class II (BMI 35–40), and Class III (BMI >40) has shown an increasing risk of stillbirth with increasing level of obesity [21].If pre-pregnancy obesity is also combined with excessive weight gain during pregnancy there is even higher risk of adverse pregnancy outcomes.

A population- based cohort study by Yao R,Ananth CV, Park By, et al (2014) conducted in 2014, conclude that there is a pronounced increase in the risk of stillbirth with increasing BMI; the association is strongest at early- and late- term gestation periods [12]. Extreme maternal obesity is a significant risk factor for stillbirth.

Another recent research by Jacob L, et al conducted in 2015; Risk of stillbirth in pregnant women with obesity in the United Kingdom , this is retrospective cohort study. A total of 44,060, pregnant women with or without increased BMI who gave birth to single child were examined using a Disease Analyser database. This study conclude that BMI increase was associated with an increase in stillbirth OR, from 1.37(95% CI 1.02-1.85) in the overweight group to 5.04(95% CI 1.79-14.07) in the group of pregnant women with BMI higher than or equal to 50. Pregnant women with obesity and even moderate overweight exhibit an increased risk of stillbirth in UK over 20 years [22].

Malaysia Association For Study of Obesity 2011 report conducted by Mini Sood from Universiti Teknologi MARA in 2011.From the study, a retrospective data of 200 pregnant women from May to June 2010 collected and conclude that a twofold increased in antepartum stillbirth was found in morbidly obese women as compared to women with normal BMI. The stillbirth rate was 7% in obese pregnant women as compared to 0.7% in normal pregnant women with *p* value 0.001[23].

2.2 STUDY JUSTIFICATION

Hospital Sultanah Bahiyah Alor star Kedah is one of tertiary hospital in the region of North of Malaysia. The total numbers of delivery between July to December 2009 is 5257. While the total number of stillbirth is 49 from 5257 of total numbers of births with stillbirth rate is 9.1.

Based on literature which are mainly western data, the obesity is currently a worldwide epidemic and the incidence of obesity among pregnant mother is rising in developed world. The perinatal complication from obesity also recognised, in which one of that is stillbirths. However the pathophysiology of stillbirth in obese women still unclear. However the is no study among Kedah population regarding the incidence of obesity in pregnant lady. Therefore this study is performed to obtain the local data from Hospital Sultanah Bahiyah mainly regarding maternal obesity and stillbirths and its association. Beside that, to get local data that represent our own population with a different sociodemographic background compare to western population. As there is no similar study conducted in North region of Malaysia it is ethical to conduct this study.

3.0 OBJECTIVES OF THE STUDY

3.1 General Objectives

1. To determine the association of obesity and stillbirth in Hospital Sultanah Bahiyah.

2. To review the risk factors of stillbirth in Hospital Sultanah Bahiyah Alor Setar.

3.2 Specific Objectives

1. To determine the proportion of stillbirth among obesity mothers.
2. To review the incidence of obesity among mother who experience stillbirth in Hospital Sultanah Bahiyah Alor Setar.

4.0 RESEARCH METHODOLOGY

Study design, venue and duration

This was a retrospective study, which was conducted in the Obstetrics and Gynaecology Unit, Hospital Sultanah Bahiyah Alor Setar Kedah for a period of 5 years (January 2011- December 2015).

Reference Population

The reference populations were all antenatal patients who delivered at Labour Room, Obstetrics and Gynaecology unit more than 22 weeks period of gestation from January 2011-December 2015.

Source Population

The source populations were all antenatal patients who delivered at Labour Room, Obstetrics and Gynaecology unit more than 22 weeks period of gestation from January 2011-December 2015.

Study Sample

All pregnant women more than 22 weeks period of gestation who delivered and fulfilled the inclusion and exclusion criteria.

Sample Size Calculation

1) Prevalence of stillbirth among obesity mother.

Sample size estimation was performed using population proportion formulae

(Lemeshow, Hosmer, Klar, Lwanga and Organisation, (1990) with level of significant α

0.05 and precision is 5% with an additional 10% dropout rate.

$$\text{Sample size } (n) = \frac{\left(Z_{1-\frac{\alpha}{2}}\right)^2 p(1-p)}{d^2}$$

where n = sample size,
Z = level of confidence,
α = alpha,
p = expected prevalence or proportion, and
d = precision.

Values used for this study: Mini Sood, Nurul Atiqah, Nur Anis, Malaysia Association

for study of obesity 2011 report.

Z : 1.96 (For the level of confidence 95%, which is conventional, Z value is 1.96)

P : 7% (0.07)

d: 5% (0.05)

10% dropout rate

Thus, estimated sample size: 101

Corrected sample size: 113

2) Incidence of obesity in pregnant population

Values used for this study: TY Leung, TN leung, DS Sahota, OK Chan, LW Chan, TY Fung, TK Lau. Trends in maternal obesity and associated risks of adverse pregnancy outcomes in a population of Chinese women. BJOG: 2008; 115; 1529-1537

Z : 1.96 (For the level of confidence 95%, which is conventional, Z value is 1.96)

P : 15.8% (0.158) - based on WHO classification

d: 5% (0.05)

10% dropout rate

Thus, estimated sample size: 205

Corrected sample size: 228

3) To determine the risk of stillbirth among obese mother

Variables:

Obesity measures in BMI (categorical obese/non-obese) – independent variable

Stillbirth (categorical yes/no) – dependent variable

Sample size calculation:

2 proportions approach by using PS Software

Parameter needed for calculation:

Significance level 0.05

Power of test 0.80

: Proportion of stillbirth among non-obese mothers

 Expected proportion of stillbirth among obese mothers

Ratio (m): 1

Sample size calculation:

Significance level (0.05	**Power of test (1 -):** 0.80	**Ratio (m) :** 1	**P_0 (Proportion of stillbirth among non-obese mother):** 0.007 (**citation)	**Calculated sample size per group:** 145 pregnant mothers	**Calculated sample size 2 groups:** 290 pregnant mothers	**Calculated sample size with 20% drop-out rate:** 348 pregnant mothers
			P_1 (Expected proportion of stillbirth among obese mother): 0.07			

The required sample size to fulfill the third objective is **348 pregnant mothers when considering 20% of drop-out rate.**

**required citation where the value of P_0 was taken

Output from PS Software:

We are planning a study of independent cases and controls with 1 control(s) per case. Prior data indicate that the probability of exposure among controls is 0.007. If the true probability of exposure among cases is 0.07, we will need to study 145 case patients and 145 control patients to be able to reject the null hypothesis that the exposure rates for case and controls are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. We will use an uncorrected chi-squared statistic to evaluate this null hypothesis.