OUTCOME OF LATE TERM PREGNANCY IN HOSPITAL UNIVERSITI SAINS MALAYSIA, KUBANG KERIAN, KELANTAN.

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Dissertation Submitted In Partial Fulfillment of the Requirement for Degree of Master Of Medicine (Obstetrics & Gynaecology)

UNIVERSITI SAINS MALAYSIA
2020

1.0 PRELIMINARIES

1.1 Acknowledgements

"In The Name of Allah, Most Gracious, Most Merciful"

All praises to Allah, the most merciful and beneficent, and peace be upon our best teacher, Prophet Muhammad S.A.W. Thank you Allah for the wisdom bestowed upon me, the strength, the good health and the perseverance to finish this research.

First and foremost, my heartiest gratitude to my supervisors, **Associate Professor Dr Nik Ahmad Zuky Nik Lah** and **Dr Wan Abu Bakar Yusoff**, Lecturers and Specialists in the Department of Obstetrics and Gynaecology, Hospital Universiti Sains Malaysia for their kind assistance, encouragement and guidance to make this dissertation possible.

To my biggest supporter, my beloved husband, **Wan Ahmad Asyraf bin Wan Md. Adnan**, thank you for always believing in me and without you by my side, this journey might not meet an end. My lovable children who served as my inspiration to complete this undertaking, thank you for all the sacrifices. Thank you to my parents, parents-in-law and siblings for their continuous prayers and inspiration.

Last but not least, I'm highly indebted to all lecturers and fellow colleagues for their constant support and help in making this dissertation a reality.

Siti Fatimah Abd. Azman

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1.3 List of Abbreviations

ACOG	American College of Obstetricians and Gynaecologist
AFD	Acute fetal distress
AFI	Amniotic fluid index
AS	Apgar score
BMI	Body mass index
BW	Birthweight
CRL	Crown-rump length
CS	Caesarean section
EDD	Estimated delivery date
EMLSCS	Emergency lower segment Caesarean section
HUSM	Hospital Universiti Sains Malaysia
IOL	Induction of labour
JEPeM	The Human Research Ethics Committee of USM
LMP	Last menstrual period
LSCS	Lower segment Caesarean section
MAS	Meconium aspiration syndrome
MOH	Ministry of Health
MREC	Medical Research Ethics Committee
MSAF	Meconium-stained amniotic fluid
NICE	National Institute of Clinical Excellent
NICU	Neonatal intensive care unit
O&G	Obstetrics and Gynaecology
OVD	Operative vaginal delivery
PPH	Postpartum haemorrhage

RCOG	Royal College of Obstetricians and Gynaecologist
RCT	Randomized control trial
REDD	Revised estimated delivery date
SOGC	Society of Obstetric and Gynaecologists of Canada
SVD	Spontaneous vaginal delivery
SVD	Spontaneous vaginal delivery
TTN	Transient tachypnoea of newborn
UK	United Kingdom
US	Ultrasound
USA	United States of America
USM	Universiti Sains Malaysia
WHO	World Health Organization

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1.6 Abstrak

Objektif: Kandungan yang jangka masa lewat 7 hari (late term) adalah diagnosis biasa dalam dunia obstetrik dikaitkan dengan morbidity yang signifikan kepada ibu dan bayi. Tujuan kajian ini adalah untuk menilai kelaziman serta keputusan kandungan bagi ibu dan bayi yang lahir lewat dari jangkaan di Hospital Universiti Sains Malaysia (HUSM).

Kaedah kajian: Kajian retrospektif ini dijalankan di Unit Obstetrik dan Ginekologi selama 5 tahun, dari 1 Jaunuari 2015 hingga 31 Disember 2019. Ia melibatkan 324 wanita hamil dengan kandungan tunggal yang jangka masa lewat 7 hari. Data sosiodemografi pesakit, cara bersalin, keputusan kandungan bagi ibu dan bayi yang lahir lewat dari jangkaan adalah termasuk dalam kajian ini.

Keputusan: Jumlah kelaziman kandungan yang jangka masa lewat 7 hari adalah 8.7% (4008 pesakit). Daripada 324 jumlah pesakit, 144 (44.4%) perlu menjalani kaedah induksi. Terdapat 269 pesakit (83.0%) bersalin secara normal (spontaneous vertex delivery), 12 pesakit (3.7%) secara mengguna alat bantuan pembedahan untuk melahirkan melalui vagina (obstetric vaginal delivery), dan 43 pesakit (13.3%) bersalin secara pembedahan. Kelaziman kejadian tumpah darah dan trauma pada perineum adalah 4.9% dan 0.6% masing-masing. Bagi keputusan keadaan bayi, 6.5% perlu dimasukkan ke unit rawatan rapi, dan 2.5% bayi mempunyai skor Apgar yang rendah (kurang dari 7 pada minit ke 5). Walaubagaimanapun, terdapat hubungan yang signifikan antara cara bersalin dan keputusan bayi (kemasukan ke unit rawatan intensif dan skor Apgar yang kurang dari 7 pada minit ke 5) dengan kelaziman yang lebih tinggi didapati pada ibu yang melahirkan secara alat bantuan pembedahan (instrumental delivery) melalui vagina.

Kesimpulan: Kajian ini mendapati kelaziman morbiditi ibu dan bayi untuk kandungan yang jangka masa lewat 7 hari (late term) adalah lebih rendah berbanding kajian-kajian lain yang pernah dilaporkan.

1.7 Abstract

Objective:

Late term pregnancy is associated with an increased risk of morbidity towards parturient and fetus. This study aims to address the number of cases and outcome of maternal and perinatal morbidity in late term pregnancy.

Methodology:

This was a retrospective study, a review of intended studied pregnancy at 41 weeks involving 324 patients who delivered at late term in the past five years at HUSM. Data involving socio-demographic of the patients, method of induction, mode of delivery, the outcome of delivery as well as maternal and fetal complications were recorded and analysed.

Results:

The number of cases of late term pregnancy was 8.73%. Out of 324 patients, 144 of them (44.4%) were induced into labour. There were 269 patients (83%) delivered via spontaneous vertex delivery, 12 patients (3.7%) via operative vaginal delivery and 43 patients (13.3%) via lower segment Caeserean section. The incidence of postpartum hemorrhage and perineal trauma were 4.9% and 0.6% respectively. In terms of fetal outcomes, 6.5% was admitted to neonatal intensive care unit following delivery, and 2.5% had their Apgar score of less than 7 at 5 minutes. There was a significant association between mode of delivery and fetal outcome (neonatal intensive care unit admission and poor Apgar score at 5 minutes) with higher incidences found in patients delivered via operative vaginal delivery. Mothers who delivered via operative vaginal delivery were

more likely to have baby admitted to NICU and Apgar score less than 7 with the odd ratio 9.11(95% Cl:2.44,33.93) and 17.6(95% CI:3.63,85.28) respectively.

Conclusion:

Our study found that the number of cases of maternal and perinatal morbidity in late term pregnancy was lower compared to previously reported figures from other studies.

2.0 INTRODUCTION

The concept of 'term' gestation guides clinicians and influences the public's perceptions about the optimal timing of delivery for a healthy pregnancy. Late-term pregnancy is defined as one that has reached between 41 weeks and 41 weeks and six days (287 days) whereas a postterm pregnancy refers to a pregnancy that has reached or extended beyond 42 weeks (294 days) of gestation from the last menstrual period (LMP) ('Practice Bulletin No. 146: Management of Late-Term and Postterm Pregnancies', 2014).

It is difficult to determine the true prevalence of late term pregnancy because inaccurate pregnancy dating tends to over-estimate incidence, and induction of labour at late term will reduce rates of postterm pregnancy (Huntly *et al.*, 2010). The incidence of late term pregnancy varies from 10-15% (Simpson and Stanley, 2011; Linder *et al.*, 2017). Data according to reports regarding postterm pregnancy published in United Kingdom and the USA was 4.4-5.3% (Weiss *et al.*, 2014). In Malaysia, the only reported study was regarding postdate pregnancy in which the population of study include women in pregnancy after 40 weeks of gestation which accounts for about 20% in the general population (Karalasingam *et al.*, 2015). Current practice in Malaysia is to induce labour at 41 weeks which has resulted in a lower percentage of postterm pregnancy.

Most late term pregnancy have unknown aetiology. The most common cause of prolonged pregnancy is incorrect dating. Ultrasound (US) estimation is at least as accurate as last menstrual period (LMP) or more, although it tends to provide younger gestational age and utilisation of both methods usually provides the most accurate dating (Maoz *et al.*, 2019). Sonographic evaluation of gestational age during pregnancy has been used to add precision. Dating of pregnancy by the last menstrual period (LMP), even when recalled with confidence, results in considerable dating error, with overestimation of gestational age. Measurement of the crown-rump length (CRL) at early pregnancy ultrasound has been shown to give a more accurate estimate of gestational age and reduces the incidence of prolonged pregnancy (Simpson and Stanley, 2011). However, ultrasound has a degree of error: 7 days up to 20 weeks' gestation, 14 days between 20 and 30 weeks and 21 days beyond 30 weeks (Simpson and Stanley, 2011). It is for this reason that the National Institute of Clinical Excellence (NICE) recommends a dating ultrasound examination between 10 and 13 weeks to estimate the gestation of pregnancy.

It was largely reported that perinatal mortality increases as pregnancy extends beyond full term, particularly after 41 weeks (Joseph, 2011; Mya *et al.*, 2017). The main reason was due to increases in both non-anomalous stillbirths and early neonatal deaths (Elden *et al.*, 2016). Progressive uteroplacental insufficiency is believed to be the predominant cause, but this remains unproven. An increase in placental apoptosis (i.e. programmed cell death) which has been shown to complicate pregnancies with intrauterine growth restriction, may contribute to the increased morbidity associated with prolonged pregnancies (Weiss *et al.*, 2014). Oligohydramnios resulted in both intrapartum cord compression and increased viscosity of meconium-stained amniotic fluid, thus increasing the risk of intrapartum fetal heart rate abnormalities and meconium aspiration syndrome

(Simpson and Stanley, 2011; Weiss *et al.*, 2014). This indicates placental insufficiency and is associated with increased perinatal morbidity.

The risks of prolonged pregnancy are mainly fetus-related, which can be divided into 2 categories. First are those associated with decreased uteroplacental function resulting in oligohydramnios, reduced fetus growth, passage of meconium, asphyxia and, potentially stillbirth. The second are those associated with continued normal placental function resulting in continued fetal growth with a subsequent increased risk of trauma during birth, including shoulder dystocia, neonatal clavicle fracture and obstetrical brachial plexus injury (Joseph, 2011; Simpson and Stanley, 2011; Slack *et al.*, 2019).

Recent evidence suggests that there may be a fundamental difference between the postterm fetus and the term fetus, more than just the longer duration of pregnancy. Studies has shown that this postterm fetus tend to have reduced plasma cortisol levels compared to similar term neonates who have elevated cortisol levels, following delivery. This may be due to an intrinsic difference in postterm infants, reducing their response to the physiological and metabolic stress of labour and delivery, compared to term infants. A relative adrenocortical insufficiency may contribute both to a delay in the onset of labour and an increased risk of intrapartum hypoxia or death if pregnancy continue beyond estimated delivery date (EDD) (Simpson and Stanley, 2011).

Full placental development, final thickness, and specific functioning are achieved between the end of the fourth and the early fifth month of gestation. From thereafter until birth, signs of gradual placental ageing are observed which are partly compensated by an increase in the number of trophoblastic villi and surface area of vasculosyncytial membranes to maintain adequate fetal oxygen and nutrient supply (Vorherr, 1975).

The effect of prolonging pregnancy on short-term neonatal outcome is controversial. Perinatal mortality rises from 0.7 to 5.8% between 37 weeks and 43weeks and six days of gestation and the nadir of neonatal morbidity and mortality appears to be around 39–41 weeks of gestation (Maoz *et al.*, 2019). Post-maturity syndrome or dysmaturity complicates 10–20% of postterm pregnancy. It is a particular clinical syndrome exhibited by neonates delivered after a pathologically prolonged pregnancy (Simpson and Stanley, 2011; Maoz *et al.*, 2019). Post-maturity syndrome consists of a number of clinical features, in which the fetus appear wrinkled, patchy, and peeling of the skin. Skin wrinkling can be particularly prominent on the palms and soles. Other features include a long, thin body suggestive of muscle wasting, and advanced maturity because the infant is open-eyed, unusually alert, and appears old and worried.

According to our hospital protocol, patient with low-risk pregnancy will be admitted to the hospital for delivery at 41 weeks of gestation. The cervical scoring will be done to assess the feasibility of induction of labour. The aim of the present study is to describe the outcome of late term low-risk pregnancy.

3.0 LITERATURE REVIEW

3.1 Background

The incidence of late term pregnancy may vary by population as a result of differences in regional management practices for pregnancies that go beyond the estimated date of delivery.

Late term pregnancy are associated with an increased risk of perinatal morbidity and mortality (Caughey *et al.*, 2007). Progressive uteroplacental insufficiency is believed to be the predominant cause of the increased perinatal morbidity and mortality rate associated with prolongation of pregnancy. Indeed, several studies over the last 60 years have shown that perinatal mortality and morbidity tend to rise when a pregnancy goes beyond 42 weeks (Abotalib *et al.*, 1996). The longer the gestation extends beyond term, the higher is the likelihood for development of placental insufficiency, fetal growth restriction, and hypoxic event (Vorherr, 1975).

Placental function and placental reserve capacity play important roles in prolongation of pregnancy. Despite the decreased rate of placental growth in the third trimester, various adaptive mechanisms mean that the placenta can still considerably increase its functional capacity (Weiss *et al.*, 2014). Some reports have suggested a link between postterm pregnancy and placental 'ageing' or maturity, and between placental maturity and perinatal morbidity. Placental maturity is manifested by a decrease in hormone production, increase in proapoptotic agents and telomere shortening in the placenta (Linder *et al.*, 2017).

The most important factors impacting prevalence of prolonged pregnancy is whether early ultrasound assessment of gestational age is performed routinely, as this tends to reduce the prevalence compared with menstrual dating(Weiss *et al.*, 2014; Middleton, Shepherd and Crowther, 2018) .The expected due date (EDD) is based on an ultrasound examination performed before 22+0 weeks of gestation if the ultrasound-based EDD differs from that calculated from menstrual dating (last menstrual period) by more than five to seven days. If the ultrasound-based EDD is within five to seven days of the LMP-based EDD, then LMP is used to determine EDD. Exceptions to this approach include pregnancies with known dates of conception/implantation, such as in pregnancies conceived by in vitro fertilization.

Apart from that, several risk factors for late term pregnancy that have been identified by observational studies, including nulliparity, prior late term pregnancy, carrying a male fetus, and maternal obesity ('Practice Bulletin No. 146: Management of Late-Term and Postterm Pregnancies', 2014). Nulliparous women more often delivered at 41 and 42 weeks compared with 40 weeks in a retrospective study entitled 'Forty Weeks and Beyond: Pregnancy Outcomes by Week of Gestation' (Alexander, McIntire and Leveno, 2000). It has been reported that the infants of primiparous women are at considerably higher risk of adverse outcome in postterm pregnancy than those of multiparous women (Lindegren *et al.*, 2017). A study by Kortekaas et al., 2015 entitled 'Recurrence rate and outcome of postterm pregnancy, a national cohort study' reported that women with a previous postterm delivery are at risk of recurrent postterm delivery (Kortekaas *et al.*, 2015).

3.2 Mode of delivery

3.2.1 Caeserean section and OVD

Between 40 weeks gestation and 41 + 6 weeks gestation the rate of Cesarean sections increased from 20 to 34% and the rate of operative vaginal deliveries rose almost continuously from 8.5 to 15.5% (Weiss *et al.*, 2014). Although operative vaginal delivery may be performed, as infrequently as in 1.5% of deliveries in some countries, it may be as high as 15% in other countries. In the United Kingdom, the rates of instrumental vaginal delivery range between 10% and 15% and these rates have remained fairly constant, although there has been a change in preference of instrument (Hubena, Workneh and Siraneh, 2018). A study by Alexandra et al., 2000, reported that the method of delivery was related significantly to weeks of gestation, with increased operative vaginal delivery and Caesareans section seen at 41 and 42 weeks (Alexander, McIntire and Leveno, 2000). The increased Caesarean rates could be attributed to labour dystocia, macrosomic fetus and non-reassuring fetal heart rate.

In a retrospective cohort study by Linder et al.,2015, it was found that mothers in the postterm group had significantly lower parity, a higher rate of instrumental deliveries and a higher rate of interventions for nonreassuring fetal heart rate than mothers in the full term and late term groups (Linder *et al.*, 2017).

Induction of labour was associated with a lower rate of Caeserean section in the Cochrane systematic review, though the pooling of results is questionable because of the heterogeneity of the included RCTs regarding the a prior risk on Caeserean

section(Middleton, Shepherd and Crowther, 2018). Different inclusion criteria regarding Bishop score, timing of IOL, upper limit of allowed gestational age in the expectant management group and different protocols for methods of induction were used, which complicated the interpretation of the results (Keulen *et al.*, 2019).

Caughey et al., 2007 reported that the indication of nonreassuring fetal heart rate for Caesarean was 1.8 times more likely at 40 weeks as compared to 39 weeks, which increased to 2-fold beyond 41 weeks even when controlling for maternal age, parity, ethnicity, education, induction of labour, use of epidural, and birth weight (Caughey *et al.*, 2007).

3.3 Maternal outcome

Interestingly, a study by Maoz et al., 2018 found that prevalence of postterm pregnancy was higher in grand multiparity (para 5 or more) compared to term pregnancy (Maoz *et al.*, 2019). This study also found that lack of prenatal care was more common among women in postterm group (Maoz *et al.*, 2019). It was assumed that more prenatal care visits and strict antepartum fetal surveillance may have decreased postterm pregnancy rates, due to enforcement of guidelines for earlier labour induction, as well as due to accurate dating.

3.3.1 Perineal laceration

A study by Caughey et al., 2007 entitled 'Maternal and obstetric complications of pregnancy are associated with increasing gestational age at term' reported that when the rates of maternal complications of labour and delivery were examined by week of gestation, the rates of third or fourth degree perineal lacerations, postpartum haemorrhage, chorioamnionitis, and prolonged labour were all increased among women delivering at 40 weeks compared to 39 weeks of gestation. This study also found the rate of third or fourth degree perineal lacerations increased from 38 to 39 weeks, and with each incremental week thereafter (Caughey *et al.*, 2007).

Women with a spontaneous vaginal delivery experienced statistically significant increased rates of third or fourth degree perineal laceration from 39 weeks (1.9%) to 40 weeks (2.2%) to 41 weeks (3.6%) through 42 weeks and greater (Caughey *et al.*, 2007). The rates of postpartum haemorrhage increased similarly by week of gestation with both

trends being statistically significant (P .001) (Caughey *et al.*, 2007). The higher incidence of third or fourth degree lacerations, secondary postpartum haemorrhage, and prolonged labour must also be interpreted as a result of increased numbers of neonates with a birth weight of more than 4000 g.

3.3.2 Postpartum haemorrhage

Although a few studies showed no differences in maternal and fetal outcomes when IOL has to be performed in late term pregnancy, expert opinions vary concerning this issue (Thangarajah *et al.*, 2016). A study by Hubena et al., 2018 showed the commonest maternal complication is postpartum hemorrhage (3.3%) and this can be explained by genital tract laceration which account for 62.5% of the PPH and prolonged labour also contributes PPH secondary to uterine atony(Hubena, Workneh and Siraneh, 2018).

3.3.3 Maternal anxiety

In addition, women with prolonged pregnancies have been shown to suffer from considerable psychological morbidity. Pregnancy is perceived by many women as becoming high risk once the estimated date of delivery is passed, leading to increased maternal anxiety (Simpson and Stanley, 2011).

3.3.4 Risk of instrumental delivery

A clinical study of postdated pregnancy by Chaudhari *et al.*,2017 showed that induction of labour was associated with a reduction in the incidence of normal vaginal delivery and an increased incidence of operative vaginal delivery (Chaudhari *et al.*, 2017).

3.3.5 Increased risk of operative vaginal delivery and Caeserean section

Mode of delivery was not significantly associated with postterm pregnancy compared with term pregnancy (Fahim Ara *et al.*,2019). The result was similar to a study by Chaudhari *et al.*, 2017. Another study also suggested that routine induction of labour at 41–42 weeks gestation is not associated with an increased risk of caesarean section and adverse maternal outcome (Otoide *et al.*,2017).

3.4 Fetal outcome

3.4.1 Fetal macrosomia

If placental function remains unimpaired after the estimated due date has passed, this will lead to increasing fetal weight gain. Although most fetus in late term and postterm pregnancies are appropriately grown for their gestational ages, pregnancies in this gestational age range are associated with an approximately twofold increased risk of macrosomia. The higher incidence of macrosomia contributes to the increased risks of operative vaginal delivery, Caesarean delivery, and shoulder dystocia ('Practice Bulletin No. 146: Management of Late-Term and Postterm Pregnancies', 2014). A similar finding was reported by Linder et al., 2017, where mean birth weight and head circumference of fetus increased with increasing gestational age at delivery when comparing the gestational age at birth: full term, late term and postterm (Linder *et al.*, 2017). Guideline by Weiss et al.,2014 found higher rates (20–25%) of neonates with a birth weight of 4000 g in the group of newborns delivered at 42 weeks gestation as compared to neonates born at 40 weeks gestation. From 41 weeks gestation, the risk of a birth weight of more than 4499 g is 3.5 times higher compared to delivery at term (OR = 3.5; 95 % CI: 3.4–3.7)(Weiss *et al.*, 2014)we. This carries obstetrical risks for both the mother and the fetus (protracted labor, operative vaginal delivery, extended maternal soft-tissue injuries, shoulder dystocia, neonatal clavicular fracture, brachial plexus injury).

3.4.2 Meconium-stained amniotic fluid (MSAF)

MSAF complicates 8 to 20% of pregnancies, and its incidence is directly proportional to gestational age at delivery. Respiratory morbidity is the most significant neonatal pathology related to MSAF, and its most significant form, meconium aspiration syndrome

(MAS), develops in 5 to 10% of cases. MSAF is recognised as a risk factor for fetal distress, thus close fetal surveillance is required if MSAF is detected during labour (Wong, Chow and Ho, 2002; Hiersch *et al.*, 2016). It is also suggested that MSAF is related partly to fetal gut maturity and other neonatal complications, including sepsis, seizures, neurologic impairment, and prolonged neonatal intensive care unit (NICU) hospitalisation (Wong, Chow and Ho, 2002; Hiersch *et al.*, 2017). MSAF was noted significantly higher in nulliparity, gestational age at delivery more than 41 weeks, induction of labour, non-reassuring fetal heart rate, and associated with operative deliveries. In multivariate analysis MSAF was associated with operative delivery (odds ratio [OR], 1.82; 95% confidence interval [CI], 1.63–2.09; $p < 0.001$), Caesarean section (OR, 1.48; 95% CI, 1.31–1.69; $p < 0.001$), respiratory morbidity (OR, 4.74; 95% CI, 3.87–5.82; $p < 0.001$), and increased risk for short-term neonatal morbidity (Hiersch *et al.*, 2016). A study by Hiersch et al., 2016 on MSAF to assess the association of gestational age at delivery with perinatal outcome in low-risk term deliveries complicated by MSAF found that late term pregnancy is associated with significant risk for neonatal respiratory morbidity (Hiersch *et al.*, 2017).

3.4.3 Perinatal death

Cochrane review on induction of labour for improving birth outcomes showed that a policy of labour induction at or beyond 41 completed weeks is associated with significant fewer perinatal deaths (22 trials, 9383 participants, RR 0.31 [95% CI 0.12-0.88]) although the absolute risk of perinatal death is small (Middleton, Shepherd and Crowther, 2018). The same findings reported by Linder et al.,2017 found the overall rate of neonatal death in the cohort of low-risk term neonates was approximately 0.1% (0.98 per 1000 live

newborns), with no significant difference among three gestational age groups (full term, late term, postterm) (Linder *et al.*, 2017).

3.4.4 Other neonatal morbidities (NICU admission, Apgar score less than 7 at 5 minutes)

In concordance with previous reports, a study entitled 'Immediate perinatal outcomes of postterm deliveries' by Maoz et al., 2018 reported that postterm delivery is more likely to be complicated with oligohydramnios, macrosomia, meconium-stained amniotic fluid, shoulder dystocia, and low Apgar scores (Maoz *et al.*, 2019). Many studies reported that rates of NICU admission, infectious morbidity, thrombocytopenia, hypoglycaemia and polycythaemia were lowest in the full-term group and steadily increased with increasing gestational age at delivery (Alexander, McIntire and Leveno, 2000; Linder *et al.*, 2017). However a study by Linder et al., 2017 found that there were no differences among the groups in rates of birth trauma, prolonged hospitalisation, respiratory distress syndrome (RDS), Meconium aspiration syndrome (MAS), hyperthermia, need for phototherapy or neurological morbidity (Linder *et al.*, 2017). Relatively few studies have addressed the long term outcome of infants born after prolonged pregnancy although the long term physical growth and intellectual development seems to be normal(Simpson and Stanley, 2011).

3.5 Management

3.5.1 Induction of labour

Much controversy surrounds management recommendations for the otherwise uncomplicated late term pregnancy, particularly when the patient has an unfavourable cervix as determined by Bishop score (Sanchez-Ramos *et al.*, 2003). Although several randomised controlled trials (RCTs) have compared labour induction with expectant management in patients with late term pregnancies, many had a relatively small number of participants. In addition, these studies' findings are conflicting (Sanchez-Ramos *et al.*, 2003). Local management practices such as scheduled IOL, differences in the use of early ultrasound (US) for pregnancy dating, and elective Caesarean section (CS) rates will affect the overall prevalence of late term pregnancy (Galal *et al.*, 2012).

American College of Obstetricians & Gynaecologists (ACOG 2014) stated that induction of labour between 41 and 42 weeks of gestation can be considered. It was concluded that induction of labour after 42 weeks and by 42 weeks and six days of gestation is recommended given the evidence of an increase in perinatal morbidity and mortality ('Practice Bulletin No. 146: Management of Late-Term and Postterm Pregnancies', 2014). Induction of labour is the process of artificially stimulating the uterus to start labour. It is usually performed by administering oxytocin or prostaglandins to the pregnant woman, or by artificially rupturing the amniotic membranes. It is not without a risks, and many women find it uncomfortable (Organization, 2018).

A recent Cochrane registry report suggests that induction of labour at 41 completed weeks gestation is associated with fewer perinatal deaths, risk ratio (RR) of 0.31 (95% CI: 0.12 to 0.88) and significantly fewer caesarean deliveries (RR 0.89; 95% CI: 0.81 to 0.97) compared with expectant management. The number needed to treat to prevent one perinatal death was 410 (95% CI: 322 to 1492). Other benefits of induction include fewer cases of meconium aspiration syndrome (Middleton, Shepherd and Crowther, 2018).

3.5.2 Induction of labour vs expectant management

Several RCTs have compared induction of labour to expectant management in pregnancies that have progressed beyond their estimated date of delivery. INDEX trial (induction of labour at 41 weeks versus expectant management until 42 weeks), a multicentre, randomised trial could not show non-inferiority of expectant management compared with induction of labour in women with uncomplicated pregnancies at 41 weeks; instead a significant difference of 1.4% was found for risk of adverse perinatal outcomes in favour of induction, although the chances of a good perinatal outcome were high with both strategies and the incidence of perinatal mortality, Apgar score <4 at five minutes, and NICU admission low (Keulen *et al.*, 2019). In a study done in Nigeria which suggest that routine induction of labour at 41–42 weeks' gestation is not associated with an increased risk of instrumental delivery, caesarean section or adverse maternal outcome (Otoide and Okonofua, 2001). The results of this study also found that routine induction of labour at 41-42 weeks gestation is not associated with an increased risk of fetal morbidity when compared with spontaneously initiated labour of similar gestation (Otoide and Okonofua, 2001). In contrast, a study by Alexander et al., 2000 concluded

that routine induction of labour with oxytocin at the completion of 42 weeks would likely increase labour complications with little or no infant benefit (Linder *et al.*, 2017).

3.5.3 Prevention of late term pregnancy

Cochrane Review did not consider that regular coitus around EDD resulted in a reduction of the duration of pregnancies of more than 41 weeks and a lower rate of induction of labour (Middleton, Shepherd and Crowther, 2018). Prophylactic weekly membrane stripping is also an option from 38 weeks gestation onwards. Although some studies have reported that stripping is beneficial and involves no risks, because of the potential pain stripping can cause, its use should be limited to selected cases.

4.0 RATIONALE OF THE STUDY

There was no study conducted in Malaysia regarding incidence of late term pregnancy. The present study is conducted with an aim to evaluate the number of cases of late term pregnancy and maternal profile in HUSM.

In addition, there is limited study looking at the outcome of adopting the policy of induction of labour at 41 weeks as recommended by ACOG and SOGC. By conducting this retrospective study, we can addressed the related morbidities to the mother and baby delivered at late term pregnancy in our local population, and later to formulate strategies to improve our management for a better outcome. We can also be able to create awareness regarding the impact of late term pregnancy among management team at local clinic or tertiary centre.

The information gathered from this study would help in terms of counselling part and educating the pregnant mother regarding risk of prolongation of pregnancy as well as risk associated with induction of labour. This would help the pregnant mother to adhere to the local protocol of induction of labour to prevent prolonged pregnancy beyond 42 weeks.

5.0 RESEARCH QUESTIONS

1. What is the number of cases of late term pregnancy in HUSM.

2. What is the outcome of delivery in a patient with late term pregnancy, including maternal and neonatal outcomes?

6.0 OBJECTIVE

General objectives

To address the outcomes of perinatal and maternal morbidity and mortality in late term pregnancy.

Specific objectives:

1. To determine the number of cases of late term pregnancy in HUSM.
2. To determine the number of cases of mode of delivery, postpartum haemorrhage and perineal trauma in late term pregnancy.
3. To determine the number of cases of baby admitted to the Intensive care unit following delivery in late term pregnancy.
4. To determine the number of cases of poor Apgar score (less than 7 at 5 minutes of life) of the baby following delivery of late term pregnancy.
5. To determine number of cases of meconium-stained amniotic fluid in late term pregnancy.

7.0 RESEARCH METHODOLOGY

7.1 Study Design, Study Venue and Study Duration

This is a retrospective observational study. It was conducted in the Obstetrics and Gynaecology Department, HUSM. The research was done from June 2018 to May 2020 including preparation of proposal and getting the approval, data collection, data analysis, and write up.

7.2 Reference and Source Population

The reference population is all pregnant women who admitted to HUSM for delivery. From this reference, all late term pregnant women in HUSM between 1st January 2015 and Disember 2019 were included in this study.

7.3 Sampling frame, Sampling Unit, Study sample:

From all late term pregnant women from 1st January 2015 and Disember 2019, patients who fulfil the inclusion criteria were included, whereas those with incomplete data and lethal congenital abnormalities were excluded.

Inclusion criteria:

- All late term pregnancy women who were admitted to HUSM for delivery (41 week until 41 week and 6 days).
- Regular menses (first dating scan correspond with period of amenorrhea) or revised EDD (REDD) given during first trimester scan.
- singleton, viable pregnancy with vertex presentation

Exclusion criteria:

- case record with incomplete data
- lethal congenital abnormalities

7.4 Sampling Methods

The method of sampling was a case notes review. A list of late term pregnant women from 1st January 2015 until December 2019 was obtained from the record office registry after getting permission from Hospital Director. Average of 64 patients were recruited for each year for 5 years using convenient sampling method. Patient's records were reviewed, and the patient's information was documented in the patient's clinical form. Data was collected in 4 categories, which included patient's demographic data, labour and delivery details, maternal and fetal morbidity outcomes. Details of each case was then recorded using the data collection form/proforma. The date for late term pregnancy were identified and analysed.

7.5 Determination of Sample Size

a) Specific objective 1(incidence)

Sample size for the incidence of late term pregnancy was calculated based on a previous study by Linder et al., 2017, which reported incidence of late term pregnancy was 19.7% (Linder *et al.*, 2017). The following formula was used to calculate the sample size .

n = sample size

$n = \left(\frac{z}{\Delta}\right)^2 p(1-p)$

Z = statistic for a level of confidence

P = expected prevalence or proportion

Δ = precision

Values used for this study:

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

P= 19.7% (0.19)

Δ= 5% (0.05)

Thus, the estimated sample size was 243 patients. However, considering the drop out as 20%, the corrected sample size was 292 patients.

b) Specific objective 2,3,4 & 5 (maternal and fetal outcome)

The sample size calculation based on Linder et al and Caughey et al. (Caughey *et al.*, 2007; Linder *et al.*, 2017).

Table 1: Sample size

Variables	**Previous study**	**Calculated sample size (with 20% drop out)**
Incidence	P 19.7% (Linder et al)	292
SVD	P 84.6% (Linder et al)	248
OVD	P 6.7% (Linder et al)	289
CS	P 8.6% (Linder et al)	212
NICU admission	P 3.4% (Linder et al)	150
Birth injury	3.3% (Linder et al)	150
A/S <7 at 5 mins	P 0.08% (Linder et al)	115
MSAF	P 12.8% (Linder et al)	195

Table 2: Sample size

Variables	**Previous study**	**Calculated sample size (with 20% drop out)**
PPH	P 4.1% (Caughey et al)	196
Perineal trauma	P 6.7% (Caughey et al)	281

Therefore, based on the calculated sample size about 292 subjects are needed for analysis.

7.6 Definition of Operational Terms

Gestational age was estimated from the date of the last menstrual period and amended by means of ultrasonography in the first trimester. If the LMP-estimated due date was not consistent with the due date obtained from the sonographic growth measurements (>7 days in the first trimester, >14 days in the second trimester, and >21 days in the third trimester), then the ultrasound-obtained due date was used to define gestational age. In cases of in vitro fertilisation, gestational age was determined according to the date of embryo transfer (Hiersch *et al.*, 2017).

Term pregnancy

Early term: 37 0/7 weeks through 38 6/7 weeks. Full term: 39 0/7 weeks through 40 6/7 weeks. Late term: 41 0/7 weeks through 41 6/7 weeks. Postterm: 42 0/7 weeks and beyond ('Practice Bulletin No. 146: Management of Late-Term and Postterm Pregnancies', 2014)

Caesarean section (CS): is a surgical procedure in which incisions are made through a woman's abdomen and uterus to deliver her baby.

Operative vaginal delivery (OVD): refers to any usage of an instrument either forceps or vacuum to extract the fetus from the vagina, with or without the assistance of maternal pushing.

Primary postpartum haemorrhage (PPH): defined as blood loss of 500 ml or more of blood from the genital tract within 24 hours of the birth of baby. PPH can be minor (500-1000ml), or major (more than 1000ml). Major could be decided to moderate (1000-2000ml), or severe (more than 2000ml).