A PROSPECTIVE RANDOMISED CONTROL STUDY ON LABOUR PERFORMANCE WITH DATES CONSUMPTION

BY

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A dissertation submitted in fulfilment of the requirement for the degree of Master of Obstetrics & Gynaecology

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ABSTRACT

This research sought to evaluate the cervical ripening before the onset of labour which is an important factor in predicting the labour performance. The objectives were to determine the effect of dates fruit on duration of labour, cervical ripening and estimated intrapartum blood loss. This randomised control trial was performed in 144 women with a singleton pregnancy, cephalic presentation at gestational age of 36 weeks. The study was conducted in Hospital Sultan Ismail, Johor and Hospital Tengku Ampuan Afzan, Pahang. The subject were randomly assigned into intervention and control group (72 women in each group).The intervention group consumed 5 pieces of dates (70-75gram per day) from 36 weeks of gestation till the onset of labour pain. The control group received the routine care. Data analysed done using independent t-test and chi square. Outcome of the study shows, the mean Bishop score at admission was higher in intervention group (8.39 ± 1.525) compared to control group (6.99 ± 2.624) which is statistically significant ($p<0.001$).The duration of labour is shorter in intervention group (247.96 ± 159.53 minutes) compared to control group (390.83 ± 202.36 minutes) ($p<0.005$). Estimated blood loss in intervention group is lesser (308.33 ± 151.75 ml) compared to control group (411.11±128.16 ml) ($p<0.005$). In conclusion, women consuming dates antenatally have better cervical scoring, shorter duration of labour and less blood loss. Dates is recommended as a supplement for pregnant women in the last weeks of gestation.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master of Obstetrics and Gynaecology.

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DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

Nor Fadzilah binti Noor Affendi

Signature ..... Date .....

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Alhamdulillah, thanks to Allah for giving me strength and ability to complete this dissertation and also the idea choosing this topic. The idea started after I read the meaning of Surah Maryam during my first pregnancy to my son, Umar. And it amaze me that the act of Maryam r.a taking the dates is explained scientifically .Subhanallah.

Firstly, it is my utmost pleasure to dedicate this work to my dear mother who always give me her endless support. My late father who leaving us with the interminable spirit to do the best in life and of course my great family. My special gratitude goes to my beloved husband, Ismail bin Isa, and my children Umar, Khadija and another little soul inside my womb for their sacrifice, understanding and support throughout the period of my study.

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CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND OF THE STUDY

فَأَجَاءَهَا الْمَخَاضُ إِلَىٰ جِذْعِ النَّخْلَةِ قَالَتْ يَا لَيْتَنِي مِتُّ قَبْلَ هَٰذَا وَكُنتُ نَسْيًا مَّنسِيًّ

فَنَادَاهَا مِن تَحْتِهَا أَلَّا تَحْزَنِي قَدْ جَعَلَ رَبُّكِ تَحْتَكِ سَرِيًّا

وَهُزِّي إِلَيْكِ بِجِذْعِ النَّخْلَةِ تُسَاقِطْ عَلَيْكِ رُطَبًا جَنِيًّا

فَكُلِي وَاشْرَبِي وَقَرِّي عَيْنًا ۖ فَإِمَّا تَرَيِنَّ مِنَ الْبَشَرِ أَحَدًا فَقُولِي إِنِّي نَذَرْتُ لِلرَّحْمَٰنِ صَوْمًا فَلَنْ أُكَلِّمَ الْيَوْمَ إِنسِيًّا

(Surah Maryam , verses 23-26)

"And the pains of childbirth drove her to the trunk of a pal, tree. She said," Oh, I wish I had died before this and was in oblivion, forgotten."

But He called her from below her, "Do not grieve; your Lord has provided beneath you a stream

And Shake toward you the trunk of the palm tree; It will drop upon you ripe, fresh dates

So eat and drink and be contented. And if you see from among humanity anyone, say,"Indeed, I have vowed to the most merciful abstention, so I will not speak today to [any] man."

Dates fruit, a reinforcing fruit rich in carbohydrates and has vast benefits particularly in pregnancy and delivery as emphasized in many Islamic tradition.

According to the results of Al-Kuran, Al-Mehaisen, Bawadi, Beitawi and Amarin, (2011), in his study which comparing cervical dilatation in a group consuming date fruit shows that the dates fruit activates oxytocin receptors, this will stimulate the uterine muscles to respond more contentedly to oxytocin and formulated a better preparation for delivery.

In current practice oxytocin is normally used to control bleeding post-delivery, in a recent non randomized clinical trial that compared date fruit and oxytocin after placenta delivery; as a result of the presence compounds in date fruit that mimicked the action of oxytocin, the dates fruit consumption expressively reduced the amount of bleeding in the first hour following the third stage of delivery which is placental delivery compared to oxytocin. (Khadem, Sharaphy, Latifnejad, Hammod, & Ibrahimzadeh, (2007). Consumption of dates fruit also recited in Al- Quran surah Maryam verse 23 -26, advise of delivery manner of Maryam (Peace be upon Her), fresh dates fruit was given to the Maryam in the time of giving birth. Based on Islamic Hadiths, if date fruit was not an amusing food source, Allah would not have given it to Maryam. Subhanallah and Allah knows the best!

1.2 PURPOSE OF THE STUDY

This research was to investigate the benefits of dates fruits on delivery performance which includes the cervical ripening before active phase of labour, durations of labour, and blood loss upon delivery process. Few studies since 2007 had done particularly in Saudi Arabia but until to date, there is no local study done regarding the matter. Dates content which is organic is fairly safe for the pregnant mother and this study is done to determine the effects of dates specifically for uterine activity during delivery.

1.3 RESEARCH OBJECTIVES

The study aimed to reach the following objectives:

General objective:

I. To determine the cervical score on admission of date fruit consuming pregnancy and non-dates consumer.

Specific objectives:

I. To compare the duration of between two groups

II. To determine the estimated blood loss between two groups.

1.4 RESEARCH HYPOTHESES

H1 There is significant difference in outcome of labour performance among date fruit consuming pregnancy compared to control group.

1.5 SIGNIFICANCE OF THE STUDY

This study will help to find a supplement that can promote cervical ripening and prevent the postpartum haemorrhage. Dates is from natural source, easily available, cheap and without adverse effect. It is also popular and well accepted among our population.

The cautious use of oxytocin for cervical ripening or induction of labour is a fairly safe procedure. However in some developing countries reported where inappropriate use of oxytocin or insufficient monitoring upon its usage cause substantially increases the risk for adverse outcomes (Khalil et al., 2004; Jeffery, Das, Dasgupta, & Jeffery, (2007). Thus it is worth to investigate the benefits of dates fruit as it can promotes the cervical ripening and reduce bleeding post-delivery. (Khadem et al., 2007)

1.6 DEFINITIONS OF TERMS

Bishop Score

It is an assessment to determine the favorability of the cervix which includes five components during vaginal examination which are cervical dilatation, cervical position, cervical effacement and consistency, and fetal station. The total score is 13.Bishop score ≤ 5 point towards an unfavorable cervix, and it is favorable if ≥ 8. (Rampersad & Macones, 2012)

Duration of Labour

Duration of labour in this study is started from time of admission to labour room to delivery of fetus.

Estimated Blood Loss

It is an estimation blood volume that loss during the delivery including vaginal and surgery.

1.7 CHAPTER SUMMARY

In this chapter, the background of the study been presented and discussed. It explained how dates scientifically helps in favouring the cervical dilatation and promotes the contraction of uterus thus reducing the blood loss based on previous research. Additionally, the purposed of the study mentioned by advocating the healthy and beneficial dates fruit intake that favours the delivery. Research and its objectives has been depicted .The significance of the study followed, emphasizing how this study can promotes the natural way of delivery by reducing the need of induction and reduced

the incidence of postpartum haemorrhage. At the end of this chapter, the limitations of the study were stated, followed by the brief definitions of the key terms that have been used in this study.

CHAPTER TWO

LITERATURE REVIEW

Up to date, prostaglandin and oxytocin are the choice of drugs that commonly used to stimulate uterine contraction. This includes induction or augmentation of labour, particularly when latent stage of first stage of labour become prolonged. Date fruit is rich with saturated and unsaturated fatty acids which are oleic, linoleic, and linolenic acids. Fatty acids can provide and reserve energy and eventually contribute to prostaglandin provision hence, date fruit can be beneficial in strengthening uterine muscles and saving the energy. Besides, it also contains hormones which aid the uterine stretching and to be prepared for delivery process (Baliga, Baliga, Kandathil, Bhat, & Vayalil, (2011).

In a study by Al-Kuran et al. (2011), few findings suggest the effect of date that favour the delivery. First, cervical dilation of women at admission of labour suite was significantly increased in the date fruit group compared with the non-date fruit group. Second, the rate of spontaneous labour was a significantly higher in the date fruit group compared with the non-date fruit group. Third, low requirement of oxytocin drugs in date fruit group in which only 28% of women in the date fruit group require the drugs compared to 43% in the non-date fruit group. Fourth, the duration of latent phase was shorter in date fruit group compare to the non-date fruit group with 38% shorter in duration.

Although oxytocin is routinely used to control postpartum bleeding, in a current non randomised clinical trial that compared date fruit and oxytocin after placenta delivery, the amount of bleeding is significantly reduced in the date fruit consumption group compared to oxytocin in the first hour following placental

delivery, this is likely owing to the compounds in date fruit that mimicked the action of oxytocin (Khadem et al., 2007).

The aim of this study was to investigate delivery parameters including the cervical dilatation, labour progress and also the estimated blood loss in two groups of women on the basis of their consumption before labour and the labour outcome of both groups in local population, Malaysia.

CHAPTER THREE
RESEARCH METHODOLOGY

3.1 INTRODUCTION

We conducted a prospective randomised controlled trial study on antenatal patients who visited 'Klinik kesihatan' and had their deliveries at Hospital Sultan Ismail (HSI), Johore and Hospital Tengku Ampuan Afzan (HTAA), Pahang from August 2015 to November 2016. The study discontinued once the targeted sample size achieved.

3.2 INCLUSION AND EXCLUSION CRITERIA

The study population involved all primigravida with singleton pregnancy and cephalic presentation. The patient recruitment started from 36 weeks of gestation.

Those patient who had planned for caesarian section earlier for any reason were excluded from the study. Other exclusion criterias include suspected big baby (fetal estimated weight more than 4kg), serious maternal medical problems and pregnancy complications (severe hypertension, uncontrolled gestational diabetes, pre-eclampsia).

3.3 STUDY IMPLEMENTATION

Patient Information and Consent Form

Patient attending the antenatal clinic were given explanations regarding the study. They informed regarding the goals, methods, benefits and possible risks or the study. The written consent will obtained from participant. The participant understood clearly that she can withdraws from the study at any time without penalty or loss resulting in her being deprived of necessary treatment.

Randomization

The subjects were randomly divided into two groups which were intervention (A) and control groups (B). They were only be known by their identification numbers. A separate list containing the subjects' particular were kept confidential.

In group A, subjects were given 5 pieces of dates per day until delivery .The compliance was monitored through the phone calls and diary on weekly basis until delivered.

In group B, patient received normal antenatal care without giving dates. They were then followed up until delivery and delivery outcomes were documented. Duration of labour were taken from the time of admission in labour room to delivery, thus each phase of labour was not taken separately but was put together as total duration of delivery.

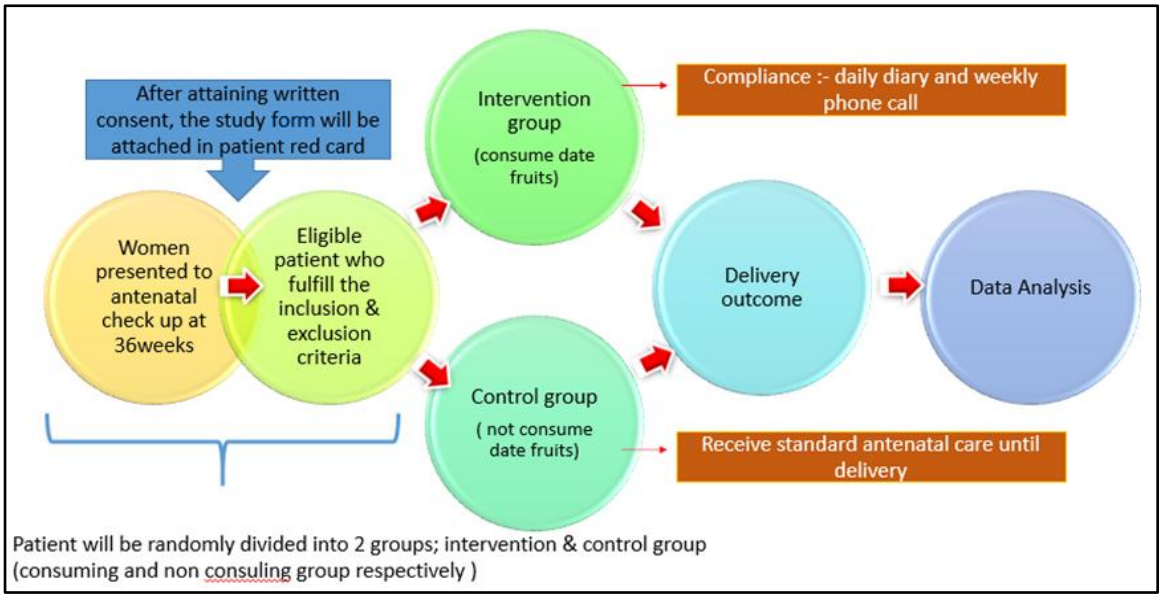

Figure 3.1 Flow chart of the study

3.4 DATA ANALYSIS

The sample size was calculated using software PS and the estimated sample size for each group was 72.

Statistical significance of the comparison were evaluated by independent t test and chi-square test and p value of < 0.05 is taken as the statistical significance.

CHAPTER FOUR

RESULTS

A total of 144 patient were recruited within the study of period in which 72 were in control group another 72 in dates consumes group (intervention group).

Table 4.1 Socio-demographic characteristic respondent (N=144)

Baseline Characteristic	Group A	Group B	P value
Age	26.33 (4.189) [a]	27.51 (3.378) [a]	0.065
Gestation at delivery (weeks)	38.52 (1.0796) [a]	39.24 (1.3696) [a]	0.001
Body Mass Index (BMI)	30.09 (4.428) [a]	31.71 (4.719) [a]	0.035
Fetal Weight (kg)	3.018 (0.369) [a]	3.1704 (0.296) [a]	0.007
Ethnicity (%)			
Malay	66 (91.66) [b]	67 (93.06) [b]	0.774
Chinese	4 (5.55) [b]	3 (4.17) [b]	0.715
Indian and others	2 (2.27) [b]	2 (2.78) [b]	0.159

[a] Mean (SD), [b] N (%)

The baseline characteristic for both group were homogeneously distributed in term of age, BMI, fetal weight and ethnicity. However for mean gestational age at delivery, in group A has shorter duration of pregnancy by mean difference of 0.72 weeks, which is statistically significant.

Table 4.2 Mean bishop score on admission in each group

Admission parameter	Group A (N =72)		Group B (N=72)		P value
	Mean	SD	Mean	SD	
Bishop score	8.39	1.525	6.99	2.624	<0.001

The result of independent T test shows that the mean Bishop score was significantly higher in the Group A.

Table 4.3 Requirement of Induction of labour in each group

	Group A (N =72)		Group B (N=72)		P value
	Mean	SD	Mean	SD	
Requirement of induction of labour	1.00	0.00	0.86	0.348	0.001

Table 4.3 shows, none of participants in Group A requiring induction of labour as compared to Group B with mean of (0.86 ±0.348) and it was significant.

Table 4.4 Mean total duration of labour (in minutes) in each group

Labour progress	Group A (N=72)		Group B (N=72)		P value
	Mean	SD	Mean	SD	
Duration of labour (minutes)	247.6	159.53	390.83	202.36	0.001

The duration of labour in Group A is shorter compared to Group B, which is 142.875 minutes faster compare to control group.

Table 4.5 Mean of estimated blood loss (in milliliter) in each group

Blood loss	Group A (N=72)		Group B (N=72)		P value
	Mean	SD	Mean	SD	
Estimated blood loss (ml)	308.33	151.75	411.11	128.16	0.001

The average of bleeding rate in both group was analysed in mean using independent t test. The result shows significantly lower blood loss in Group A with 102.78 ml lesser compared to Group B.

Table 4.6 Outcome of delivery

Delivery Outcome	Group A (N = 72)	Group B (N = 72)	P value
Vaginal delivery	63 (51.2 %)	60 (48.8 %)	P = 0.479
Caesarean section	9 (42.9%)	12 (57.1)	

There were no significant different in mode of delivery in both groups. Although the Group A has less percentage of caesarean section, however it was not significant. (χ^2 (df = 1) = 0.502, P = 0.479).

Out of 9 caesarean section in intervention group (Group A), 7 were due to fetal distress.Only two cases were due to poor progress of labour. In control group (Group B) out of 12 caesarean section, 6 cases were due to fetal distress. The other 5 were due to poor progress and one case due to failed instrumentation.

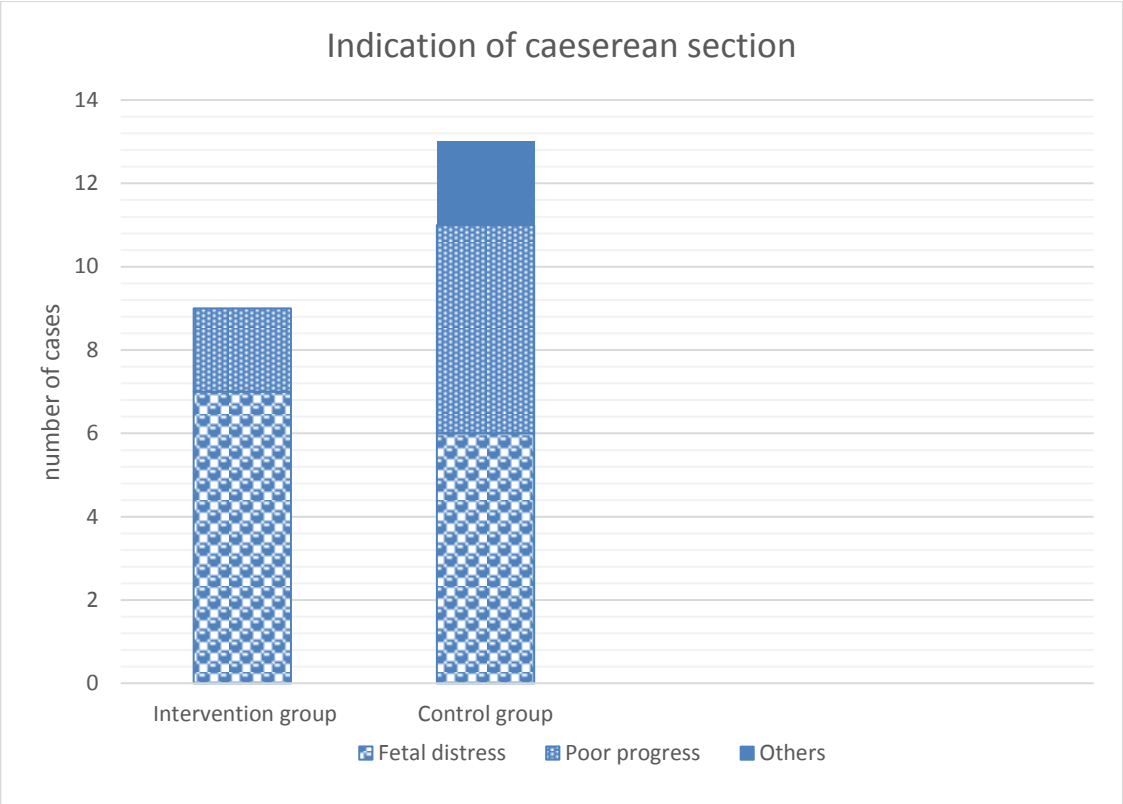

Figure 4.1 Chart showing the indication of caesarean section in both intervention and control group

Table 4.7 Neonatal outcome

Neonatal outcome	Group A (N=72)		Group B (N=72)		P value
	Mean	SD	Mean	SD	
Apgar Score at 5 minutes	8.1528	0.685	8.2917	0.721	0.238
Admission to NICU	0.0139	0.11785	0.0139	0.11785	1.00

All patient who were recruited has no serious medical illness and had uneventful antenatal follow up. Neonatal outcome shows good Apgar score in both group (8.528 ± 0.685) in Group A and (8.2917 ±0.721) in Group B. Only two cases required NICU admission ,one case from Group A and another in Group B ,making

the cases not statistically significant (P=1.00) . Thus it shows no difference in term of neonatal outcome in intervention and control group.

Both cases who requiring Neonatal Intensive Care Unit (NICU) admission is from caesarean section cases. For Group A, the caesarean section indication was fetal distress, delivered with Apgar score of 7 at 5 minutes. Another case from group B, the indication of caesarean section was poor progress with Apgar of 7 at 5 minutes. Both cases not requiring ventilation and discharge within one week. Other cases of fetal distress were had good Apgar score and not requiring intensive care admission.