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Clinical Trial of Induction of Labor Versus Expectant Management in Prolonged Pregnancy

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ABSTRACT

The objective of this study is to compare two strategies for managing prolonged pregnancy either by immediate induction of labor at 41 weeks or expectant management until 43 weeks gestation. The study was conducted in Tripoli Medical Center (TMC) for 12 months from beginning of January 2008 to end of December 2008. 300 pregnant women after 41 weeks gestation with singleton fetus in cephalic presentation and low risk pregnancy were enrolled for the studies.

The patients in this study were selected from out-patient department (OPD) and labor ward taking the information from OPD charts.

Groups were managed expectantly depending on ante-partum fetal testing by using the following tests:

- Daily kick chart.
- Ultra sound twice weekly to measure amniotic fluid.
- Biophysical profile once weekly.
- Doppler ultra sound in some cases.

The perinatal outcome and the mode of delivery were insignificantly different in patients who were managed by induction of labor at 41 weeks gestation or expectantly up to 42 weeks gestation.

In patients managed by expected management until 43 weeks gestation the perinatal mortality and morbidity increased significantly (about three times more than 41 weeks or 42 weeks gestation).

Keywords - *Prolonged pregnancy; Perinatal mortality and morbidity; Gestation.*

INTRODUCTION

Prolonged pregnancy is a cause of anxiety for both women and obstetricians. Prolonged pregnancy is perceived as being a cause of increased risk to the fetus.[1] In addition many women find the physical burden of pregnancy at or near term to be intolerable and the concept of having to go past their estimated date of confinement unbearable.[2] Debate continues over the merits of a policy of routine induction of labor at a set gestation to avoid risks compared with a conservative "wait and see" approach.[3]

The standard international definition of prolonged pregnancy accepted by both WHO and FIGO is pregnancy that lasts greater than 294 days or more "completed 42 weeks or more",[1] from first day of last menses if menstrual cycle is 28 days.[4] Post maturity refers to the abnormal condition of the fetus or newborn resulting from a prolonged pregnancy.

It is apparent that not every post term pregnancy is complicated by the post maturity syndrome, but it is likely that the majority of morbidity and mortality associated with post term pregnancy arises because of post maturity.[2]

MATERIALS AND METHODS

This randomized prospective study was conducted in Tripoli Medical Center (TMC), which is a tertiary referral University institution that publishes an annual clinical report. TMC includes detailed data on obstetric outcome and mode of delivery on all mothers who have been delivered and all prenatal deaths.

The period of study took 12 months and started at the beginning of January 2008 till the end of December 2008. Eligible patients included pregnant women at 41 weeks or more (calculated from the first day of last menstrual period and confirmed by early ultrasound result) with singleton cephalic presentation fetus.

Patients with multifetal pregnancy, non cephalic presentation, fetal distress on admission, fetal congenital anomalies, spontaneous or induced rupture of membrane before admission, decreased amount of liquor by ultrasound measurement, maternal medical disorders with pregnancy, ante partum haemorrhage, obvious cephalopelvic disproportion, previous surgery as caesarean section, myomectomy with opened uterine cavity as well as women unsure of date and with no early ultrasound result were all excluded from the study. Participants randomized divided into three main groups and each group consisted of 100 participants.

First group: Patient managed with induction of labor at 41 weeks.

Second group: Patient managed by expectant management

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with fetal surveillance till reaching 42 weeks after that induction of labor. If spontaneous labor is started or an ante partum fetal test became abnormal, the patient was excluded from the study. Ante partum fetal tests consisted from kick chart daily, ultrasound twice weekly to measure deep vertical pool depth, CTG twice weekly, biophysical profile once weekly.

Third group: Patient presented in labor after 42 weeks (approximately 43 weeks). These patients were under care of obstetrician outside TMC and according to patient's request.

These cases were observed and studied under our supervision. We discussed with participants the benefits and the potential risks regarding the induction of labor as well as the expectant management using ante partum fetal testing. It is important to mention here that the women preferences were considered in the management plan.

Statistical analysis

Quantitative data were described using the mean while categorical data were described using the frequency (number of cases) and percentage. Comparison of categorical data was done using the Chi square test. Yates correction equation was used when any of the expected values <5. A probability value (*P* value <0.05) was considered statistically significant. Statistical calculations were done using SPSS (Statistical Package for the Social Science SPSS Inc, Chicago, IL, USA) statistical program.

RESULTS

A total of 300 women were enrolled in this study (Figures 1-4). Participants were divided into three groups according to strategy of management and time of induction each group consisted 100 participants to compare mode of delivery, perinatal mortality and morbidity in different groups.

The time of induction was different in three groups: the first group the induction of labour was done at 41 weeks, the second group was managed expectantly until 42 weeks gestation after that the induction of labour, third group also managed expectantly but until 43 weeks gestational. The frequency of each group was 100 and the percentage 33.3 from total number of participants.

Mode of delivery:

Regarding mode of delivery (Figure 1) in first group was 63% normal vaginal delivery, 10% instrumental delivery, 27% caesarean section. In the second group was 65% normal delivery, 9% instrumental, 26% caesarean section but in third group the percentage of normal delivery 51%, the instrumental about 17%, and caesarean section rate was 31%.

The perinatal outcome in the first group: about 78% of babies were healthy and discharged from hospital with good general condition, 17% were admitted to NICU and after one week 13% of them were discharged, 5% were diagnosed with mild to moderate birth asphyxia. In second group, 79% were healthy 15% were admitted to NICU among them 13% were discharged after one week, 6% were diagnosed with birth asphyxia. Neonatal seizures, intracranial haemorrhage, stillbirth, early neonatal death or mechanical ventilation support was not found in either group. A comparison between the first and second group showed no statistically difference in fetal out come (Figures 2 and 3). In third group, 64% babies were healthy, 23% were admitted to NICU, 10% were diagnosed with birth asphyxia two of them had neonatal seizures. When comparing the previous two groups with third group, we found a significant increase in neonatal morbidity and mortality, still birth and neonatal death due to neonatal seizures (Figure 4).

DISCUSSION

The ante-partum intervention of a prolonged pregnancy is still controversial. The first major issue is when to initiate intervention, at 41 or 42 weeks gestation. The second issue is what intervention should be implemented: labour induction or expectant management using ante-partum fetal testing with selective labour induction.

Although the risk of ante-partum morbidity and mortality increase with increasing gestational age, there is no evidence that allows determination of the optimal time to initiate ante-partum testing or labour induction.[5]

It has long been recognized that prolonged pregnancy is associated with excess perinatal mortality and morbidity. However, the exact risks are a matter of continuing debate.[6] In older data sets about 25% of excess mortality risks in prolonged pregnancy can be accounted by lethal congenital abnormalities, mainly due to cranial neural tube defects.

Butler and Bonham found that delivery at 42 weeks gestations associated with a doubling of the perinatal mortality rate when compared with delivery at 39-41 weeks gestation, and congenital abnormalities were not excluded.[7]

Nevertheless, this led to a doubling in the rate of early induction between 1958 to 1970, which was partly attributed to an attempt to reduce the number of prolonged pregnancy.

In an observational study of some 57000 pregnancies in Dublin, in which lethal congenital abnormalities were excluded, showed the perinatal rate did not significantly rise until 42 weeks and the intra-partum fetal death was four times more common and early neonatal death three times more common in infants born after 42 weeks gestation, from 1.57 per 1000 at 40 weeks to 3.71 per 1000 at 43 weeks. The risk of ante-partum still birth was also increased with increasing gestational age.[8]

Data from several large studies in United Kingdom reported calculated death per 1000 ongoing pregnancies and they found that ante-partum still birth rate began increasing after 40 weeks with estimates of 0.86-1.08 per 1000 before 41 weeks, 1.2 - 1.27 per 1000 between 41-42 weeks, and 1.58 - 2.12 per 1000 at 43 weeks.

In a large data set from Norway, gestational age-specific mortality rate fell progressively from completed 37 weeks

to a nadir at 40 weeks and rose thereafter, reaching a peak at 43 weeks comparison of the birth at 39-40 weeks gestation, with those achieved after 43 weeks gave an adjusted relative risk of only 1.11.[8]

Although not statistically significant in most individual trials, there is a consistent finding that perinatal mortality rate are lower with planned induction at 41 weeks or later compared with expectant management.[9] A finding confirmed by formal meta-analysis based on the observed absolute risk difference in meta-analysis, at least 500 inductions are necessary to prevent one perinatal death.[10]

Whether this is an acceptable trade-off at either policy or individual level is unclear. Other perinatal outcome did not appear to differ significantly from induction and expectant management group.

Elective labor induction before 42 weeks gestation has been proposed to reduce rate of adverse fetal and maternal complication, the Canadian multicenter post-term pregnancy trial (CMPPT) is the largest individual randomized controlled trial ~~to~~ till date comparing labour induction at 41 weeks with expectant management.[8,11]

In the mentioned study[8], 3407 women with pregnancies of at least 41 weeks gestation were randomized to immediate induction or expectant management with fetal monitoring continued until 44 weeks gestation or until there was an obstetric indication for labor induction. The expectant management group had a significantly higher rate of caesarean deliveries resulting from fetal distress, but there was no difference between groups in the rate of caesarean deliveries, but there was no difference between groups in the rate of caesarean deliveries resulting from dystocia, also no difference in perinatal mortality or morbidity.[12]

The review of many RCTs about 19 by Cochrane found that routine labour induction at 41 weeks gestation resulted in lower perinatal mortality rate but caesarean section rate, approximately three times higher by 43 weeks gestation.[7,13]

In others meta-analysis of RCTs comparing induction at 41 weeks versus expectant management, the induction group had lower caesarean delivery rates.[14]

A non significant reduction in perinatal mortality rates were also found in the induction group. Approximately 6600 women were included; approximately 1600 women were screened to detect a 50% reduction in perinatal mortality.[15,16]

The primary difference between the meta-analysis was in the studies chosen for inclusion.

Trials included in Cochare review fell into two main groups: those in which women were enrolled at or before 40 weeks gestation and those in which recruitment occurred at 41 or 42 weeks gestation.[17]

The benefit of induction was found in studies where induction occurred after 41weeks.

Not all authorities agree with induction of labour.[18]

Analysis of our results shows the perinatal mortality rate does not rise significantly till 42 weeks and early neonatal death is three times more common in infants born after 43 weeks ($P = 0.02$) (Figure 4), this pattern corresponds with the observational study of Dublin and Norway.[8]

The data of our study showed no relation between the mode of delivery and the time of intervention, this corresponds with most of previous RCTs.

Our study continues to support Cochrane review of 19 RCTs that found routine induction of labour in prolonged pregnancy resulted in lower perinatal mortality rate but similar caesarean section rate approximately three times increased by 43 week.[7]

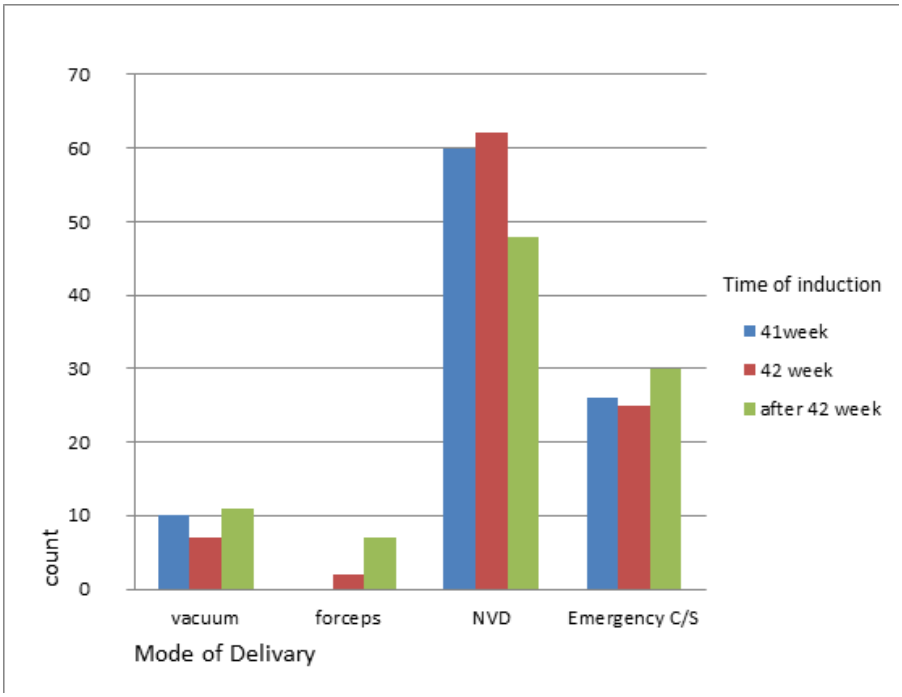

Figure 1: Mode of delivery

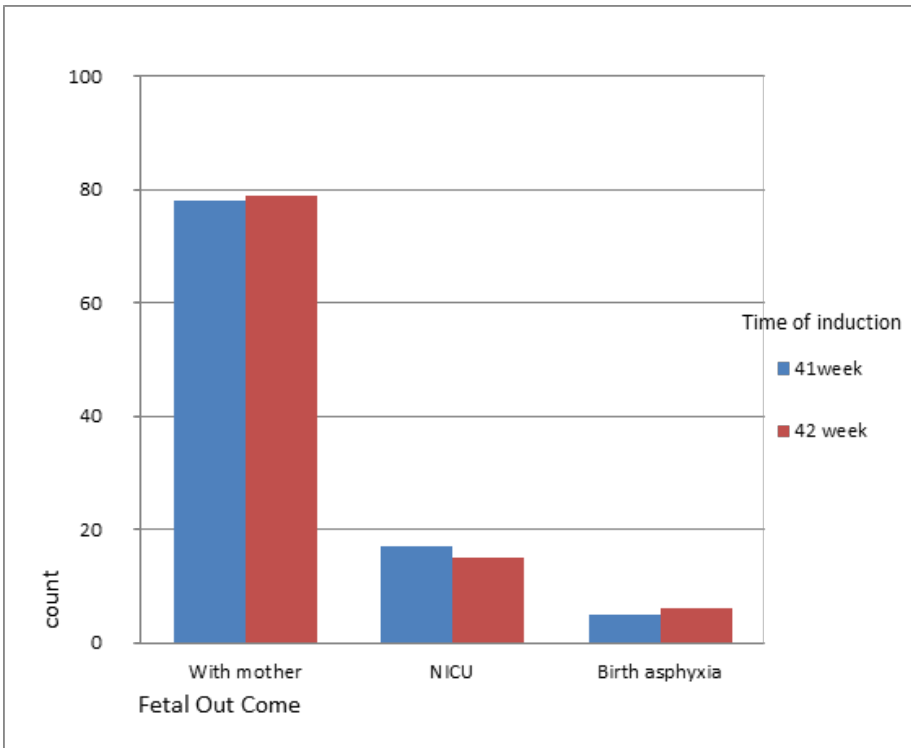

Figure 2: Fetal outcome.

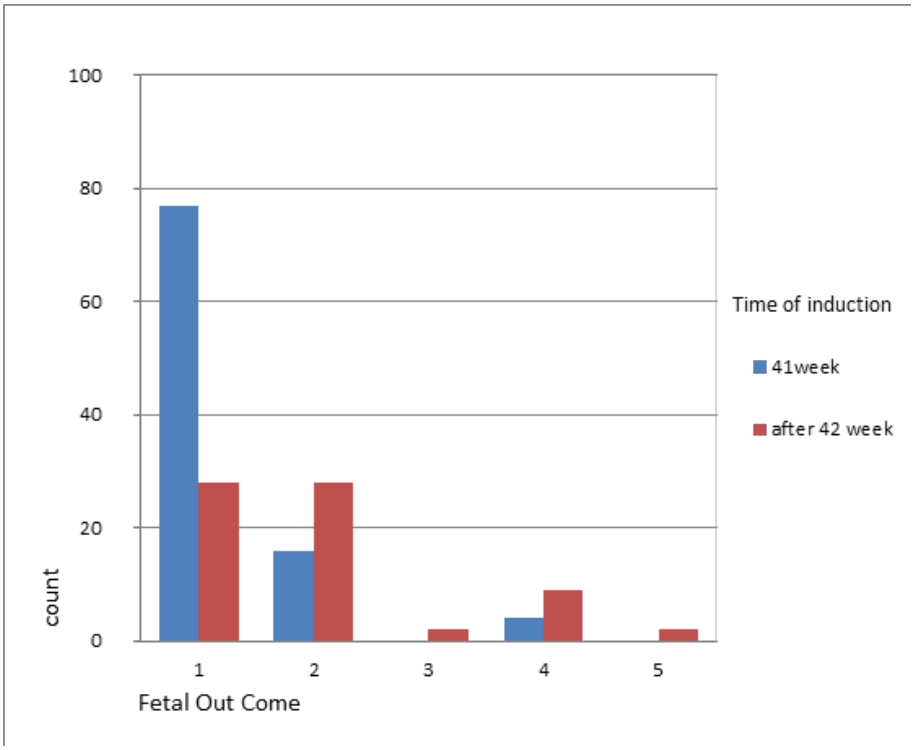

Figure 3: : Fetal outcome and time of induction for 41and after 42 weeks.

CONCLUSION

The perinatal outcome and the mode of delivery were insignificantly different in patients who were managed by induction of labor at 41 weeks gestation or expectantly up to 42 weeks gestation.

In patient managed by expected management until 43 weeks gestation the perinatal mortality and morbidity increased significantly (about three times more than 41 weeks 42 weeks gestations).

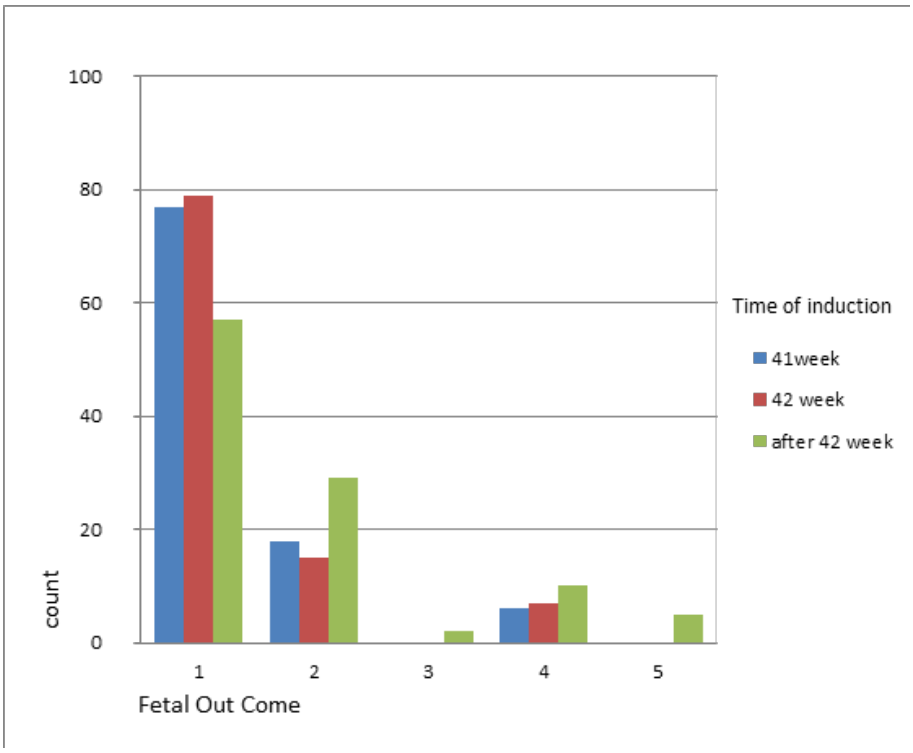

Figure 4: Fetal out come and time of induction for 41, 42 and after 42 weeks.

REFERENCES

1. NICE guideline 62 (2008) Antenatal care –routine care for the healthy pregnant woman. National willaborating center for women's and children's Health, RCOG press.
2. NICE guideline 70 (2008) Induction of labour. National collaborating centre for women's and children's Health, RCOG press.
3. Shea KM, Wilcox AS and Little RE (1998) Post term delivery: 9 challenge for epidemic research, *Epidemiology* **9**, 199-204
4. Gardosi J, Vanner T and Franus A (1997) Gestational age and induction of labor for prolonged pregnancy, *Br J obstetric Gynaecol* **104**, 792-797.
5. Crowley P (2000) Interventions for preventing or improving the outcome of delivery at or beyond term, *Cochrane Database Syst Rev* **2**, CD 000170.
6. Hilder L, Costeloe K and Thilaganathan B (1998) Prolonged pregnancy: evaluating gestation-specific risks of fetal and infant mortality, *Br J obstet Gynaecol* **105**, 169-173.
7. NGulmezoglu AM, Crowther CA and Middleton P (2006) Induction of labour for improving birth outcomes for women at or beyond term, *Cochrane Database Syst Rev* **4**, CD00.4945.
8. Hannah ME, Hannah WJ and Hellmann J *et al.* (1992) Induction of labour as compared with serial antenatal monitoring in post-term pregnancy. A randomized controlled trial. The Canadian multicenter post-term pregnancy trial group N Engl, *J Med* **326**, 1587-1592.
9. Nwosu EC, Welch CR, Manasse PR and Walkinshaw SA (1993) Longitudinal assessment of amniotic fluid index, *Br J obstet Gynaecol* **100**, 816-819
10. Mandruzzato G, Meir YI, Dottavio G *et al.* (1998) Computerized evaluation of fetal heart rate in post-term fetuses: long term variation, *Br J obstet Gynaecol* **105**, 356-359.
11. American college of obstetrics and gynecologist (ACOG) (2004) Management of post-term pregnancy. Washington (DC), *ACOG Practice Bulletin*, **55**.
12. Heimstad R, Skovall E, Mattsson LA *et al.* (2007) Induction of labour or serial antenatal fetal monitoring trial, *Obstet Gynaecol* **109**, 609-617.
13. Smith GC (2001) Life-table analysis of the risk of perinatal death at term and post-term in singleton pregnancies, *Am J obstet Gynecol* **184**, 489-496.
14. Alfirevic Z, Luckas M, Walkinshaw SA *et al.* (1997) A randomized comparison between amniotic fluid index and maximum pool depth in the monitoring of post-term pregnancy, *Br J Obstet Gynaecol*, **104**, 207-211.
15. Alfirevic Z and Walkinshaw SA (1995) A randomized controlled trial of simple compared with complex antenatal fetal monitoring after 42 weeks of gestation, *Br J Obstet Gynaecol* **102**, 638-645.
16. Fischer RL, Kuhlman KA, Depp R and Wapner RJ (1991) Doppler evaluation of umbilical and uterine – arcuate arteries in the post date pregnancy, *Obstet Gynecol* **78**, 363-368.
17. SOGC clinical practice Guidelines (2008) Guidelines for the management of pregnancy at 41+0 to 42+0 weeks, **214**.
18. Roberts LJ and Young HR (1991) The management of prolonged pregnancy- an analysis of women's attitudes before and after term, *B r J Abstet Gynecol* **98**, 1120-126.