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Original Research Article

Comparison of Early and Late Amniotomy for Induction of Labour

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Abstract: ***Background:*** Association of induction of labor with higher cesarian section rates is of particular concern. On the other hand, a few trials have shown a net reduction in cesarian section rates. ***Objective:*** To compare early and late amniotomy in terms of frequency of cesarean delivery, intrapartum fever and mean induction delivery interval in full term pregnant women. ***Methods***: The selected 190 women were randomized into two groups, Early Amniotomy Group A (n=95) and Late Amniotomy group B (n=95), through simple lottery method. In group A, oxytocin infusion and amniotomy was performed within first hour. While in group B, the oxytocin infusion (1 mU/min and increased subsequently every 30 min to 2, 4, 8 mU/min) was started but amniotomy was delayed for 4 hours. ***Results:*** The mean ± standard deviation of age was 27.59 ± 6.59 years, parity 2.86 ± 1.55, gestational age 39.86 ± 1.59 weeks, and Bishop score 8.42 ± 1.75. The induction-to-delivery interval was significantly shorter in the early amniotomy group compared to the late amniotomy group (152.64 ± 19.68 minutes vs. 312.22 ± 71.31 minutes; $p < 0.001$). Vaginal delivery occurred in 61.1% of cases and cesarean section in 38.9%, with no significant difference between the two groups ($p = 0.36$***).*** ***Conclusion:*** Early amniotomy significantly shortens the induction-to-delivery interval without increasing cesarean section rates or intrapartum fever. It may be considered a safe and effective strategy for labor induction at term when appropriate protocols are followed.

Keywords: Induction of Labour, Early and Late Amniotomy, Intrapartum Fever.

INTRODUCTION

Induction of labor is a technique where uterine contractions are stimulated for achieving the delivery before the onset of spontaneous labor. Induction of labor is considered as one of the most common obstetrical techniques used in USA. It was reported that during the decade of 1990s, that the rate of labor induction increased to more than three times, from 9.5% to 31.4%.[1] During the period from 2014 to 2023 the percentage of labor induction in early term births almost doubled, i.e. from 18% to 31%. At 37 weeks gestation births by induction of labor almost doubled, from 20.7% to 37.4%, while at 38 weeks an upsurge of 68% was observed i.e. from 16% to 27%.[2] This surge can be partly attributed to clinical indications related to maternal or fetal health, yet it was observed that a that marginally indicated and elective inductions contributed significantly to this increase.[3] A number of factors are responsible for this surge including the easier access to improved and efficient cervical ripening drugs, the desire on part of patient as well as healthcare provider to control the time of delivery according to the convenience, and a shift of attitude towards marginal indications for induction.[4] An increase in awareness of both patient and healthcare provider regarding the risk of fetal mortality associated with expectant management closer to term or post-term have led to a surge in rates of induction.

A number of societies have established standardized protocols for the induction of labor including the American College of Obstetricians and Gynecologists (ACOG)[5,6], the National Institute for Health and Clinical Excellence (NICE)[7], and the Society of Obstetricians and Gynecologists of Canada.[8]

Delivery of fetus before the spontaneous beginning of labor is considered in instances of where maternal/fetal risks of waiting for onset of labor are significantly higher than the maternal/fetal risks linked to early delivery.[9,10] In such a scenario the heath care provider is only left with two options i.e. labor induction or delivery via c-section. As cesarean delivery is often associated with a higher risk to the patient hence induction of labor is When there are no contraindications to labor and vaginal birth, induction of labor is typically recommended.

In case of early delivery, the risk to maternal/fetal health cannot be measured accurately. A number of attributes determine this risk including gestational age at the time of induction, status of fetal lung maturity, degree of the clinical severity, and the condition of cervix. It should be noted that timely induction of labor in women with specific pregnancy complications is advocated to optimize the maternal-fetal outcome[11,12], however, the currently available data is insufficient to support the benefits of induction of labor in managing specific medical and obstetrical conditions.[13]

A number of incidence where labor induction is opted include following: Post-term pregnancy, Pre-labor (premature) rupture of membranes, Preeclampsia, eclampsia, HELLP (Hemolysis, Elevated Liver enzymes, Low Platelets) syndrome, Fetal demise, Maternal diabetes, Fetal growth restriction, Twins, Chorioamnionitis, Abruptio placentae.

The most significant concerns linked to elective ("social") induction of labor at term are the associated risk of higher rates of cesarean delivery, neonatal complications lined to prematurity or early-term delivery, and economic burden. There are, however, a number of potential advantages to induction of labor, including a reduced rate of term stillbirths, macrosomia, and meconium passage.[14] In addition, with induction of labor a lower risk of delivery enroute to the hospital in patients having a history of rapid labor or patients with longer travel time (>30 minutes) to hospital. Lastly, elective induction reduces the chance of sudden disruption of the patient's (and provider's) professional and personal obligations.

Currently, there is expert consensus that elective induction should not be performed before 39 weeks of gestation; however, there are insufficient data to recommend for or against elective induction of labor at ≥39 weeks of gestation.[15-18] Randomized trials with adequate statistical power to evaluate maternal and neonatal safety and determine neonatal benefit as a reflection of reduced unexplained fetal death, as well as cost-effectiveness/cost-benefit analyses, are needed to clarify the risks and benefits of this approach. Until better data are available, we avoid elective induction of labor.

Shafqat et al., 2022 compared the amniotomy with spontaneous rupture of membranes and reported a shorter labor in amniotomy group.[19] A very limited number of studies involving the procedure of amniotomy has been recorded from Pakistan in recent years. The study compares the effect of early and late amniotomy as a therapeutic option to shorten the induction-to-labor interval.

1. Objectives and Hypothesis

The objective of the current study is to compare early and late amniotomy in terms of frequency of cesarean delivery, intrapartum fever and mean induction delivery interval in full term pregnant women.
The hypothesis of the study includes following,

1. Early amniotomy can shorten the induction-to-delivery interval.
2. There is no significant difference in cesarean section rate or intrapartum fever in early amniotomy and late amniotomy group.

3. Methods

This randomized controlled clinical trial (OBG-2011-126-4842) was conducted at Gynae& Obs. Unit I of Holy Family Hospital, Rawalpindi from 16-08-2015 to 16-02-2016. Patients meeting the inclusion criteria after informed consent were randomly assigned to early amniotomy or late amniotomy group using simple lottery method.

a. Sample size

The sample size was calculated to be approximately 95 patients in each group using WHO sample size calculator following measurements, Level of significance = 5%, Power of test = 80%, Population mean= 9.47, Test value of population mean=7.97, Pooled SD= 3.65. Non probability consecutive samples were collected.

b. Sample selection

Inclusion criteria

All women with following criteria were included; Age ≥ 18yrs, Gestational age ≥ 37 weeks to 42, Singleton pregnancy with vertex presentation, Intact amniotic membranes, a Bishop score of ≥ 6.

Exclusion criteria

All women with conditions leading to increased likelihood of C section; history of Maternal infection with hepatitis B or C, Fetal growth restriction less than 5th percentile, AFI less than 8cm or more than 25cm, Severe pre-eclampsia (BP ≥ 160/110 mmHg) with proteinuria +1, Previous cesarean section , Pre labour rupture of membranes diagnosed on per speculum examination, Women with previous administration of PGE2 or Misoprostol for induction of labor (indicating failed induction), Placenta previa diagnosed by USG, Women with any contraindication to vaginal delivery.

c. Data collection procedure

The study was carried out at Gynecology & Obs. Unit I of Holy Family Hospital, Rawalpindi. After receiving approval from the ethical committee of hospital, women admitted to the ward fulfilling the inclusion criteria were selected for the study. Study Procedure was explained to the participating women, and written informed consent was taken.

The selected women were randomized into two groups. Early Amniotomy Group A and Late Amniotomy group B, through simple lottery method. In group A, oxytocin infusion and amniotomy was performed within first hour after randomization. While in group B, the oxytocin infusion was started but amniotomy was delayed for 4 hours.

Oxytocin administration was initiated at 1 mU/min and increased every half an hour to 2, 4, 8 mU/min, then increment of 2 mU/min every half an hour as necessary depending on uterine contractions. Partogram was maintained. Intermittent fetal heart rate monitoring was done. The data in terms of rate of cesarean delivery, induction-to-delivery interval and intrapartum fever was recorded on the Performa.

d. Outcome Measures

Primary outcome: Mode of delivery / induction-delivery interval

Secondary outcomes: Intrapartum fever, maternal complications

e. Ethical Considerations

Ethical approval was sorted, written informed consent was obtained from all participants and confidentiality was maintained.

4. **Data Analysis procedure:**

Data was entered and analyzed using SPSS version 22.

All the categorical data like C section, patient febrile, frequencies along with proportions was calculated. Whereas for the continuous variable induction delivery interval in minutes, means along with range and standard deviation were calculated. Chi square test and independent sample t-test were performed for categorial and continuous variables.

To compare the proportion of c section in both study groups, chi square test at 5 % level of significance was applied (a p-value less than 0.05 was considered statistically significant).

Independent samples t-test was applied at 5 % level of significance to compare the induction delivery interval between both study groups (p-value less than 0.05 was considered statistically significant).

To compare the risks of outcomes like c section and fever in both study groups, relative risk was estimated along with 95 % confidence intervals. 95% confidence intervals were constructed for relative risk and exclusion of value 1.00 was determine the statistical significance.

Age and parity were comparable in both groups hence were not controlled for.

RESULTS

The study recruited a total of 190 subjects divided into Early amniotomy group (n=95) and Late amniotomy group (n=95). The baseline demographics and clinical characteristics for both groups were observed as follows (Table 1). The minimum age was found as 18 years and maximum age was 40 years with mean ± standard deviation as 27.59 ± 6.59 years (95% CI: 26.7–28.5). The minimum parity was found as 1 and maximum parity was 6 with mean ± standard deviation as 2.86 ± 1.55 (95% CI: 2.64–3.08). The minimum gestational age was found as 37 weeks and maximum was 42 weeks with mean ± standard deviation as 39.86 ± 1.59 weeks (95% CI: 39.63–40.09). The minimum parity was 1 and the maximum was 6, with a mean ± standard deviation of 2.86 ± 1.55 (95% CI: 2.64–3.08). The minimum Bishop score was 6 and the maximum was 11, with a mean ± standard deviation of 8.42 ± 1.75 (95% CI: 8.17–8.67). The minimum duration of labor was found as 4 hours and maximum duration of labor was 16 hours with mean ± standard deviation as 8.43 ± 3.25 hours (95% CI: 7.97–8.89).

The primary outcome of the study included induction to delivery interval (Table 2). The minimum induction delivery interval was found as 120 minutes and maximum induction delivery interval was 410 minutes with mean ± standard deviation as 232.43 ± 95.47 minutes (95% CI: 218.86–246.00).

The secondary outcomes of the study included intra partum fever and mode of delivery (Table 2). There were 95 (50%) patients in the early amniotomy group and 95 (50%) patients in the late amniotomy group. Intra partum fever was found in 22 (11.6%) patients, whereas 168 (88.4%) patients did not have intra partum fever. There were

116 (61.1%) cases of vaginal delivery and 74 (38.9%) cases of C-section. Relative risk was found to be 1.18 when comparing mode of delivery with study group, and relative risk was 0.83 when comparing study group with the presence of intra partum fever.

By using chi-square, it was found that there was no significant association between groups and mode of delivery with p-value = 0.36. By using independent samples t-test, Significant difference was found in mean induction delivery interval in both groups having p-value = 0.001.

Table 1. Descriptive Statistics of baseline demographics (n = 190)

	Minimum	Maximum	Mean	Std. Deviation
Age	18	40	27.59	6.59
Parity	1	6	2.86	1.55
Gestational Age	37	42	39.86	1.59
Bishop Score	6	11	8.42	1.75
Induction-Delivery Interval	120	410	232.43	95.47

Table 2. Primary and Secondary Outcomes for Early and Late Amniotomy Groups (n = 190)

Outcome	Group A (Early Amniotomy)	Group B (Late Amniotomy)	Total / Comparison	P-value / 95% CI
Induction-to-Delivery Interval (minutes), mean ± SD	**152.64 ± 19.68**	**312.22 ± 71.31**	–	**<0.001**
Mode of Delivery				
Vaginal	**61**	**55**	**116/190 (61.1%)**	**χ^2 = 0.84, p = 0.36**
Cesarean	**34**	**40**	**74/190 (38.9%)**	**RR = 1.18 (95% CI: 0.77–1.81)**
Intra Partum Fever	**12**	**10**	**22/190 (11.6%)**	**RR = 0.83 (95% CI: 0.38–1.81), p > 0.05**

SD: Standard Deviation; χ^2: Chi-square test; RR: Relative Risk; CI: Confidence Interval; p: probability value.

DISCUSSION

The aim of the present randomized controlled trial was to evaluate the effect of early amniotomy vs late amniotomy on the outcomes of induction of labor in full term pregnant women in terms of rate of cesarean delivery, mean induction delivery interval, and rate of intrapartum fever. For this purpose, a total of 190 full term patients were enrolled fulfilling the inclusion and exclusion criteria by using non probability consecutive sampling at Gynea & Obs. Unit I of Holy Family Hospital, Rawalpindi.

In current study the cesarian section rate was almost similar with no significant difference between both groups. This relates to previous study where cesarean delivery rate was comparable between groups (18% vs. 17% among nulliparous; and 3% vs. 0% among parous women, in early amniotomy and late amniotomy group, respectively).20,21 The induction to delivery interval was found to be significantly shorter in early amniotomy (152.64 ± 19.68 minutes) as compared to late amniotomy (312.22 ± 71.31 minutes), this is consistent with previous studies where early amniotomy lead to a shorter oxytocin-to-delivery interval (12h vs. 15h).22-24 Premature rupture of membranes can result in rapid progression of labor which in turn leads to reduction in overall duration of labor. A reduced induction-to-delivery interval can impart a significant clinical benefit, particularly in situations where prolonged labor can result in complications in maternal and fetal outcomes.

Of all 190 patients Intra partum fever was found in 11.6% patients whereas it was comparable between both EA group (12.6%) and LA group (10.5%) showing a non-significant difference. A previous study reported that decrease in intrapartum fever in EA group to LA group (3% vs. 25%) in nulliparous women was not significant (p = 0.05).23 In the present study, vaginal delivery occurred in 116 (61.1%) patients and cesarean section in 74 (38.9%) patients, with no significant difference between EA and LA groups (relative risk for cesarean: 1.18; 95% CI: 0.77–1.81). Similarly, the incidence of intrapartum fever was low and comparable between groups (RR = 0.83; 95% CI: 0.38–1.81).

Previous randomized studies have documented variable effects of early amniotomy on cesarean section. In few studies a higher cesarean section rate was reported in the early amniotomy group (e.g., 25% vs. 7.9%), primarily contributed to dystocia in most cases (15% vs. 3.3%).25,26 However, when cesarean section deliveries were omitted, difference in the duration of labor between early and late amniotomy groups was found to be non-significant (8.3 ± 3.8 hours vs. 7.7 ± 2.9 hours).27

The above studies emphasize that while in some populations cesarean risk may increase with early amniotomy, in our study, early amniotomy significantly reduced induction-to-delivery interval without increasing cesarean rates or maternal fever. These differences among studies may be due to varying patient selection, labor management protocols, and definitions of failed induction or dystocia.

Notably, earlier studies have also highlighted that early amniotomy can lead to shorter induction-to-delivery interval (13.3 vs. 17.8 hours, p = 0.001), but are often related with higher risks including chorioamnionitis (22.6% in EA vs. 6.8% in LA, p = 0.002) and fetal umbilical cord compression (12.3% in EA vs. 2.9% in LA, p = 0.017). The benefit in labor shortening was mainly reported in women receiving oxytocin increments every 30 minutes (13.3 vs. 17.8 hours, p = 0.001), whereas the higher incidence of chorioamnionitis was reported in groups with extended oxytocin intervals (60 minutes), which also showed a tendency toward a higher incidence of moderate to severe variable decelerations (19.6% vs. 6.4%, p = 0.08).24

These findings recommend that although early amniotomy can lead to shorter labor, meticulous monitoring and personalized oxytocin protocols are vital to avoid maternal and fetal risks. In the context of the present study, early amniotomy safely reduced induction-to-delivery interval without increasing cesarean delivery or intrapartum fever, highlighting its potential benefit in routine labor management when appropriate protocols are followed.

Conclusion

Early amniotomy significantly shortens the induction-to-delivery interval compared to late amniotomy in term pregnancies undergoing labor induction (p < 0.001). There was no significant difference between the two groups in terms of cesarean delivery rates or incidence of intrapartum fever. These findings indicate that early amniotomy is an effective and safe intervention for reducing labor duration without increasing maternal morbidity when appropriate labor management protocols are followed.

REFERENCES

1. Osterman MJ, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: final data for 2020. https://stacks.cdc.gov/view/cdc/112078/cdc_112078_DS1.pdf
2. Martin JA, Osterman MJ. Shifts in the distribution of births by gestational age, United States, 2014-2022. 2024. DOI: 10.15620/cdc:135610.
3. Little SE. Elective induction of labor: what is the impact?. Obstetrics and Gynecology Clinics. 2017 Dec 1;44(4):601-14. DOI: 10.1016/j.ogc.2017.08.005
4. Snowden JM, Bane S, Osmundson SS, Odden MC, Carmichael SL. Epidemiology of elective induction of labour: a timeless exposure. International journal of epidemiology. 2024 Aug;53(4):dyae088. https://doi.org/10.1093/ije/dyae088
5. American College of Obstetricians and Gynecologists. ACOG practice bulletin no. 107: induction of labor. Obstet Gynecol. 2009;114:386-97.
6. Spong CY, Berghella V, Wenstrom KD, Mercer BM, Saade GR. Preventing the First Cesarean Delivery: Summary of a Joint: Eunice Kennedy Shriver: National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, and American College of Obstetricians and Gynecologists Workshop. Obstetrics & Gynecology. 2012 Nov 1;120(5):1181-93. DOI: http://10.1097/AOG.0b013e3182704880
7. Induction of labour (CG70) www.nice.org.uk/CG70.
8. Robinson D, Campbell K, Hobson SR, MacDonald WK, Sawchuck D, Wagner B. Guideline No. 432c: Induction of Labour. Journal of obstetrics and gynaecology Canada: JOGC= Journal d'obstetrique et gynecologie du Canada: JOGC. 2023 Jan 1;45(1):70-7.
9. Swift EM, Gunnarsdottir J, Zoega H, Bjarnadottir RI, Steingrimsdottir T, Einarsdottir K. Trends in labor induction indications: a 20-year population-based study. Acta obstetricia et gynecologica Scandinavica. 2022

Dec;101(12):1422-30.
10. Hassan WN, Shallal F, Roomi AB. Prediction of successful Induction of labor using ultrasonic fetal parameters. Current Women's Health Reviews. 2022 Feb 1;18(1):134-9.
11. Hong J, Atkinson J, Mitchell AR, Tong S, Walker SP, Middleton A, Lindquist A, Hastie R. Comparison of maternal labor-related complications and neonatal outcomes following elective induction of labor at 39 weeks of gestation vs expectant management: a systematic review and meta-analysis. JAMA network open. 2023 May 1;6(5):e2313162-.
12. Hu Y, Chen B, Wang X, Zhu S, Bao S, Lu J, Wang L, Wang W, Wu C, Qi L, Wang Y. Association between timing of labor induction and neonatal and maternal outcomes: an observational study from China. American Journal of Obstetrics & Gynecology MFM. 2024 Oct 1;6(10):101456.
13. Coates D, Makris A, Catling C, Henry A, Scarf V, Watts N, Fox D, Thirukumar P, Wong V, Russell H, Homer C. A systematic scoping review of clinical indications for induction of labour. Plos one. 2020 Jan 29;15(1):e0228196.
14. Grobman WA. The role of labor induction in modern obstetrics. American Journal of Obstetrics and Gynecology. 2024 Mar 1;230(3):S662-8.
15. Vilchez G, Nazeer S, Kumar K, Warren M, Dai J, Sokol RJ. Risk of expectant management and optimal timing of delivery in low-risk term pregnancies: a population-based study. American journal of perinatology. 2018 Feb;35(03):262-70.
16. Sotiriadis A, Petousis S, Thilaganathan B, Figueras F, Martins WP, Odibo AO, Dinas K, Hyett J. Maternal and perinatal outcomes after elective induction of labor at 39 weeks in uncomplicated singleton pregnancy: a meta-analysis. Ultrasound in Obstetrics & Gynecology. 2019 Jan;53(1):26-35.
17. Grobman WA. The role of labor induction in modern obstetrics. American Journal of Obstetrics and Gynecology. 2024 Mar 1;230(3):S662-8.
18. Tita AT, Jablonski KA, Bailit JL, Grobman WA, Wapner RJ, Reddy UM, Varner MW, Thorp Jr JM, Leveno KJ, Caritis SN, Iams JD. Neonatal Outcomes of Elective Early-term Births After Demonstrated Fetal Lung Maturity. Obstetrical & Gynecological Survey. 2019 Feb 1;74(2):66-7.
19. Shafqat T, Zeb L, Yasmin S. Comparing effects of amniotomy and spontaneous rupture of membrane on duration of labor in primigravida at term pregnancy. Obstet Gynecol Res. 2022;5:181-6.
20. Gari A, Baradwan S, Tawfiq A, Hakeem G, Alkaff A, Hafedh B, Algreisi F, Latifah HM, Alyafi M, Abduljabbar HH, Alzawawi N. Early versus late amniotomy for induction of labor: a systematic review and meta-analysis of randomized controlled trials. Gynecologic and Obstetric Investigation. 2025 Mar 11.
21. De Vivo V, Carbone L, Saccone G, Magoga G, De Vivo G, Locci M, Zullo F, Berghella V. Early amniotomy after cervical ripening for induction of labor: a systematic review and meta-analysis of randomized controlled trials. American journal of obstetrics and gynecology. 2020 Apr 1;222(4):320-9.
22. Hasan NA, Hong JG, Teo IH, Zaidi SN, Hamdan M, Tan PC. Early versus delayed amniotomy with immediate oxytocin after Foley catheter cervical ripening in nulliparous labor induction: a randomized trial. International Journal of Gynecology & Obstetrics. 2022 Dec;159(3):951-60.
23. Gagnon-Gervais K, Bujold E, Iglesias MH, Duperron L, Masse A, Mayrand MH, Sansregret A, Fraser W, Audibert F. Early versus late amniotomy for labour induction: a randomized controlled trial. The Journal of Maternal-Fetal & Neonatal Medicine. 2012 Nov 1;25(11):2326-9.
24. Halouani A, Masmoudi Y, Hamdaoui R, Hammami A, Triki A, Ben Amor A. Early versus late amniotomy during induction of labor using oxytocin: A randomized controlled trial. Plos one. 2023 May 25;18(5):e0286037.
25. Levy R, Ferber A, Ben-Arie A, Paz B, Hazan Y, Blickstein I, Hagay ZJ. A randomised comparison of early versus late amniotomy following cervical ripening with a Foley catheter. BJOG: an international journal of obstetrics and gynaecology. 2002 Feb 1;109(2):168-72.
26. Berry M, Lamiman K, Slan MN, Zhang X, Goncharov DD, Hwang YP, Rogers JA, Pacheco LD, Saade GR, Saad AF. Early vs delayed amniotomy following transcervical Foley balloon in the induction of labor: a randomized clinical trial. American journal of obstetrics and gynecology. 2024 May 1;230(5):567-e1.
27. Robbins LS, Yuanfan Y, Becker D, Xue Y, Bushman ET, Battarbee AN, Szychowski JM, Tita A, Harper LM. 960 Late vs. early amniotomy for preterm induction of labor: a randomized-controlled trial. American Journal of Obstetrics & Gynecology. 2021 Feb 1;224(2):S595-6.

