# ELECTIVE INDUCTION OF LABOUR BY AMNIOTOMY—A RANDOMIZED PROSPECTIVE STUDY OF 530 PATIENTS OVER 3 YEARS

by

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*Summary*

Obstetric and Perinatal Outcome of Induction, Improved efficacy by Proper Case Selection, Influence of Cervical Score and Inducibility, Role of Oxytocin and Optimum time for oxytocic Supplementation in Failed Induction Are Discussed.

Elective induction of labour in obstetrically normal women, in and around the gestational age of 40 weeks, is an obstetric management aimed at avoiding the inherent inconvenience and risks involved in prolonged pregnancies. While Greenhill (1974) has recommended this active management as a good obstetric procedure controversy still continues over employing induction of labour as a routine obstetric procedure, (Menon, 1982). Cole *et al* (1975) could not demonstrate that elective induction contributes to medical convenience, but could prove that it helps to reduce perinatal mortality. Tipton and Lewis (1975) amongst many others from their experience of modern active management of labour conclude that high induction rate has not resulted in increased number of premature birth or operative delivery. In the study of Chalmers *et al* (1975) no advantage or disadvantages to the foetus was demonstrable following induction of labour. According to Pitkin (1976) the safety of the procedure rests with proper patient selection, and with an experienced obstetrician who adheres to strict criteria, the risk is minimal.

Eventhough the role of elective induction in obstetric practice is hotly contested we have been strong advocates of this active intervention as a standard obstetric management, over the past 3 years (Rajan and Ramani, 1981; Rajan *et al*, 1982 and Girija Leela and Rajan, 1982). There is almost uniform agreement as to the method of induction in term pregnancies, and fore-water amniotomy (A.R.M.), oxytocic infusion and PG $E_2$ by oral or vaginal route are the standard procedures (Gopalan, 1982). Combination of amniotomy and oxytocin (Cole *et al* 1975;

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Cross and Pitkin, 1978 and Beezley and Alderman, 1975) or combination of amniotomy and PG $E_2$ (Bremme and Bygdeman, 1980) have been the preference of many for effective labour induction and short induction-delivery interval. However, we employ amniotomy as the primary method of induction and supplement oxytocin only when induction with amniotomy fails. PG $E_2$ appears to be more suited to ripen the cervix and improve the inducibility of the cervix wherever the cervival score is poor (Wingerup *et al*, 1978 and Wilson, 1978). In general, amniotomy would be the choice when the cervix is favourable and there need not be any concerns regarding the alledged adverse fetal effects of this standard obstetric intervention (Pitkin, 1982).

What we are presenting is a randomized prospective study of 530 elective inductions performed around 40 weeks of gestational age in obstetrically normal women, over a period of 3 years ending with September 1982. Merits and demerits of this standard obstetric management in terms of patient convenience, induction delivery interval, operative intervention and perinatal outcome have been considered for discussion. Minimising the risk factors by proper case selection with favourable cervical score, concurrent use of oxytocin, and the optimum time for oxytocin supplementation in cases of failed induction are the other aspects considered in this study.

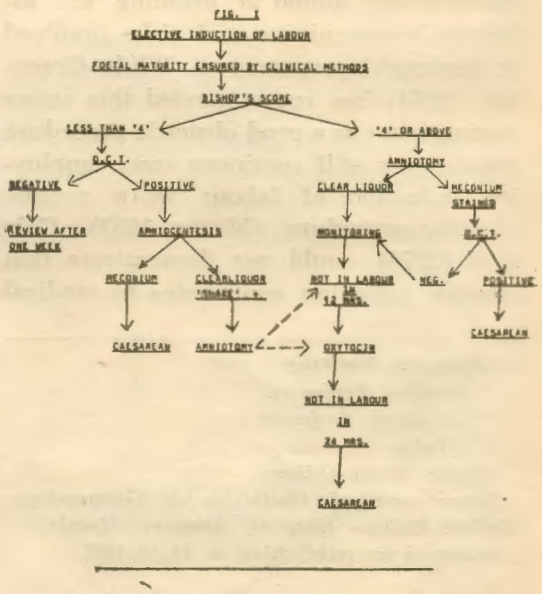
## *Materials and Methods*

The 530 patients in whom labour was induced electively at term could be devided into 3 groups:

*Group I*: Consists of 105 consecutive subjects in whom labour was induced by amniotomy irrespective of the nature of cervix and the level of the presenting part. Whether the cervix was favourable or not, amniotomy was performed and spontaneous onset of labour was awaited. If not established in labour, oxytocic infusions was started, and a failed induction at the end of 24 hours was managed by caesarean section.

*Group II*: Another 74 consecutive patients were managed almost on the same lines as group I subjects with one difference: All of them had oxytocin supplementation immediately following amniotomy. This is a group where combination of amniotomy and oxytocin was tried irrespective of the nature of cervix and the cervical score.

*Group III*: (Fig. I). This group consists of 351 subjects in whom meticulous case selection was made. Induction by amniotomy was attempted only if the Bishop score was 4 or above, and those with poor inducibility were monitored by oxytocin challenge test (OCT) every week till the cervical score had improved or OCT showed probable evidence of



foetal compromise. The management protocol for these patients is given in Fig. I. This group also did not have regular oxytocin augmentation, but it was employed only in failed inductions.

Among the 351 patients in group III, a randomly selected 139 subjects were studied for their obstetric outcome in relation to the cervical score done by the Bishop's scoring system (Bishop, 1964), and they are separately indicated as subgroup A. Another 90 patients in group II itself were monitored for uterine contractions and time of establishment of labour, with the purpose of identifying the optimum time for oxytocin supplementation in cases of failed inductions (Sub-Group B).

*Results*

This study consisted of 234 primiparous women and 296 multiparous women undergoing elective induction of labour. Induction was successful in 513 subjects (96.80%) who delivered vaginally in a range of 1 hr 50 mts to 27 hours following induction. Those who failed to establish labour contractions or developed uterine inertia, 17 subjects (3.20%), were delivered by caesarean section. There were 3 neonatal deaths in this series resulting from cord prolapse (1), meconium aspiration (1), and prematurity with RDS (1), giving a perinatal mortality of 5.7 per 1000 births. As evaluated by clinical presentation and duration of hospital stay, there was no puerperal sepsis in this group.

Behaviour pattern of the patients in the three different induction groups, induction delivery interval, incidence of caesarean section, need for oxytocin augmentation and perinatal mortality, is given in Table I. Accordingly, induction delivery was prolonged (13 hrs) and the failure rate was around 4% in group I patients in whom induction was attempted in consecutive subjects irrespective of cervical score. However, in the same type of subjects when concurrent oxytocin augmentation was employed (group II) the induction delivery interval was reduced to 9 hrs and 10 mts, with no reduction in the failure rate, incidence of caesarean section being around 4%. A well balanced improved results were obtained in group III subjects where amniotomy was performed only if cervical score was 4 or

TABLE I

*Obstetric and Perinatal Outcome in 3 Induction Groups*

| Group | Patient particulars | No. | Mean Duration of labour | Caesarean sections | Neonatal death |
|---|---|---|---|---|---|
| I | Induction by amniotomy at term, irrespective of Bishop's score | 105 | 13 hrs. | 4 (4%) | 1 |
| II | Induction by amniotomy at term, and oxytocic augmentation, irrespective of Bishop's score | 74 | 9 hrs. 10 mts. | 3 (4%) | nil |
| III | Induction by amniotomy only if score is 4 or above. No concurrent oxytocic augmentation | 351 | 11 hrs. 40 mts. | 10 (2.80%) | 2 |

above 4. The induction—delivery interval was 11 hrs. 40 mts, and the failure rate was at its lowest with 10 subjects (2.80%) requiring caesarean section. Neonatal death also followed a particular pattern. In the unselected series of 105 patients (group I) there was 1 neonatal death due to cord prolapse in a patient with mobile head, whereas in the selected group of 351 patients (group III) there were 2 neonatal deaths due to meconium aspiration and prematurity.

Influence of Bishop's score on the obstetric outcome in the 139 randomly selected patients is given in Table II. But for 3 patients who had to be induced with a poor score (score 3) because of late deceleration detected in O.C.T., the cervical score in all the subjects ranged from 4 to 9. The mean induction to delivery interval showed a steady decline from 16 hrs and 5 mts for score 3 to 10 hrs. and 51 mts for score 6, and 4 hrs, and 45 mts for score 9. Moreover, of the 39 subjects with a better score (greater than 6) 19 (48.70%) had delivered within 6 hours of induction with amniotomy. Similarly, more than 75 per cent with a Bishop's score greater than 4 had delivered within 18 hours. Pitocin augmentation was 33.33% for score 3, 30.76% for score 4 and 20% for score 5. There were 2 failures in this groups and their scores were 3 and 5.

Analysis of failed induction ending in caesarean sections revealed that among the 17 caesareans, 12 (70.50%) were for subjects with Bishop score of 3 and 4, 17.7% for score 5 and around 5% for score 6 and 7. None of the patients with score 8 and 9 had to be subjected to caesarean section (Table III).

Study of uterine contractions in 90 randomly selected subjects having Bishop's score ranging from 4 to 9 revealed the following: Uterine contractions were established shortly after induction by amniotomy and labour was completed

TABLE II

*Bishop's Score and Obstetric Outcome*

(139 Subjects)

| Score | Pts. | Duration of labour (mean) | Delivered in 6 hrs. | Delivered in 12 hrs. | Oytocin augmentation | Caesarean section |
|---|---|---|---|---|---|---|
| 3. | 3 | 16 hr. 5 mt. | nil | 1 (33.33%) | 1 (33.33%) | 1 (33.33%) |
| 4. | 13 | 14 hr. 30 mt. | nil | 4 (30.76%) | 4 (30.76%) | nil |
| 5. | 30 | 13 hr. 28 mt. | 5 (16.66%) | 14 (46.66%) | 6 (20.00%) | 1 ( 3.33%) |
| 6. | 54 | 10 hr. 51 mt. | 8 (14.81%) | 34 (62.96%) | 8 (14.81%) | nil |
| 7. | 25 | 10 hr. 10 mt. | 11 (44.00%) | 15 (60.00%) | 5 (20.00%) | nil |
| 8. | 9 | 7 hr. 12 mt. | 3 (33.33%) | (100%) | nil | nil |
| 9. | 5 | 4 hr. 40 mt. | 5 (100%) | nil | nil | nil |

TABLE III

*Bishop's Score in Failed Induction*

| Bishop Score | No. of caesarean sections | Percentage of total caesareans |
|---|---|---|
| 3 | 4 | 23.50 |
| 4 | 8 | 47.00 |
| 5 | 3 | 17.70 |
| 6 | 1 | 5.90 |
| 7 | 1 | 5.90 |
| Total: | 17 | |
| | (No failure in score 8 & 9) | |

in 6 hrs. in 24 subjects (26.67%). Another 32 subjects established labour contractions within 6 hours of amniotomy but delivered within 12 hours of induction (35.56%). Thus 62.23% of the patients delivered within 12 hours of induction. Ten more subjects (11.11%) who were in labour within 6 hours of induction delivered within 18 hours of induction. Remaining 24 patients were not established in labour by 6 hours of amniotomy, but 8 of them got into labour spontaneously within 12 hours of induction and delivered without oxytocic augmentation (33.33%); whereas the rest 16 subjects (66.67%) failed to establish labour contractions even at 12 hours and hence needed oxytocic augmentation. In otherwords, for patients not in labour after amniotomy, if oxytocic augmentation is to be started at the end of 6 hours of amniotomy 24 subjects (26.66%) would have received oxytocin, by contrast if 12 hours is taken as the failure point only 16 subjects (17.77%) would require oxytocin (as demonstrated in this study) (Table IV).

TABLE IV

*Nature of Uterine Contractions in 90 Subjects*
(Progress After Amniotomy)

| | |
|---|---|
| Delivered in 6 hours | 24 (26.67%) |
| Established labour within 6 hours, delivered within 12 hr. | 32 (35.56%) |
| Established labour within 6 hrs., delivered between 13 and 18 hours | 10 (11.11%) |
| Not established labour within 6 hours | 24 (26.66%) |
| Established labour after 6 hours and delivered spontaneously | 8 ( 8.88%) |
| Not estabished labour in 12 hours, delivered by oxytocin augmentation | 16 (17.77%) |

Birth weight of the newborns ranged from 2 to 4.20 kg, with a mean of 3.03 kg. This is almost the same birth weight recorded for spontaneous deliveries in our hospital.

*Discussion*

This study essentially involves 530 term pregnancies in obstetrically normal subjects in whom elective induction of labour was contemplated around the 40th week of gestation. Method of induction of choice in majority of subjects happened to be fore-water amniotomy, with oxytocic infusion kept in reserve for those few subjects who fail to respond to amniotomy even after 12 hours of induction.

The overall results for elective induction appears quite impressive, with the possibility of conveniently planned delivery in a good majority of the subjects at the cost of a low failure rate necessatating caesarean section in 3.20%, and the lowest minimum possible perinatal mortality of 5.7 per 1000 births. In this planned obstetric management delivery was ensured within 24 hours of amniotomy in all subjects, and the figures reveal that 1/3rd subjects deliver within 6 hours and 2/3rd subjects deliver within 12 hours. Oxytocic augmentation was required in 17.77% of subjects for successful completion of delivery. Labour was prolonged beyond 24 hours, upto 27 hours, in 6 subjects. We feel that inclusion of subjects with poor score and cervical inducibility is the factor responsible for prolonged labour and greater need for oxytocic augmentation.

While many concurrently administer oxytocic infusion following amniotomy, and even our experience with a small series of 74 subjects prove that induction-delivery interval is shortened by this combined procedure, we are not in favour of routine oxytocic augmentation.

The reasons advanced are: (i) patients with favourable cervices (Bishop score 6 and above) have a short induction delivery interval (less than 10 hours—mean), and about 50 per cent of them deliver within 6 hours. (ii) In group III subjects, where there was proper case selection, the mean delivery interval showed only a marginal increase by 2 hours over the concurrent oxytocin group (group II). (iii) Concurrent oxytocin induction failed to reduce the incidence of caesarean section (4%), whereas with proper selection (group III) the caesarean section rate could be reduced to 2.80%. We feel that when the cervix is unfavourable, judicious waiting with OCT monitoring for a more ripe cervix will be a better scientific approach than trying to induce with amniotomy and concurrent oxytocin. If the cervix continues to remain unfavourable or if there are other reasons for induction, cervical ripening with PG $E_2$ followed by amniotomy will be the most practical proposition.

We are also not convinced on the principle of initiating oxytocic infusion if the patient is not in labour within 4 to 6 hours of amniotomy. Apart from the fact that a good percentage of patients with favourable cervix deliver wihin 6 to 12 hours of amniotomy, 33 per cent of patients who are not in labour at 6 hours get into labour within 12 hours of amniotomy and deliver spontaneously. Hence by delaying oxytocic augmentation and restricting the same to only those who are not in labour at 12 hours of amniotomy the need for oxytocin could be minimised.

Analysis of the failed induction group of 17 subjects who were delivered by caesarean section suggest that attempted induction with unfavourable cervix (Bishop's score 3 and 4) was the commonest cause for failures (70.50%). As already pointed out concurrent oxytocic induction could not reduce the incidence of caesarean section. All these again point to considering only those with favourable cervix for elective induction.

After reviewing the analytical data we are convinced that the interest of a pregnant mother who is obstetrically normal is best served by elective planned induction of labour at term, and this active intervention could be considered as a standard obstetric management. Induction can be perfected by the most simple and elegant method, which is non-pharmacological too, namely amniotomy. However, further improvement in results in terms of reduced induction-delivery interval, reduced need for oxytocic augmentation, and reduced failure rate could have been obtained by strictly adhering to the principles of proper case selection. Only those with a favourable cervix (Bishop's score 6 or above) should be subjected to induction by amniotomy. Those with score 5 may be considered for induction only if other compelling reasons are there. If the cervix is unfavourable (score 4 or below) it is better to postpone induction with greater reliance on careful monitoring by O.C.T. Only if O.C.T. is positive or other signs of potential foetal risk are detected induction should be attempted, and that too only after establishing pulmonary maturity by amniocentesis. Of course, the risk of failure must be accepted unless Pg E2 could be employed for ripening the cervix. Oxytocin is not required for those with favourable cervix who by themselves are prone for short labour, and oxytocin is not helpful in those with unfavourable cervix because it does not reduce the failure rate and hence the incidence of caesarean section. Perinatal mortality is at its lowest in this series (5.7 per 1000) and probably a

furher reduction may not be possible by any improvement in the technic of elective induction. The explicit fact is that the perinatal mortality could not have been lower than this if all these 530 patients were awaiting spontaneous onset of labour, and in all probability mortality could have been higher.

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