

A trial of amniotomy in a Palestinian hospital

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Summary

This randomised controlled trial of routine amniotomy was carried out in a developing country setting to investigate the effect of this common procedure on the duration of labour, intra-partum interventions and selected newborn and maternal outcomes. In a Jerusalem teaching hospital, 533 multiparous and 157 nulliparous low-risk women were randomised to either amniotomy or intent to conserve membranes. For multiparae, the median duration from randomisation to full dilatation was 95 and 160 min, respectively in the intervention and control arms ($p < 0.001$); for nulliparae it was 210 and 270 min, respectively ($p < 0.001$). In both groups, oxytocin was used less in the intervention arms ($p < 0.001$), and no difference in mode of delivery and immediate outcomes was detected. However, given the risks of this intervention and these study findings indicating an overall short duration of childbirth, amniotomy should be limited to cases of abnormal progress of labour.

Keywords

Labour, amniotomy, Palestinian Hospital, developing country

Introduction

Amniotomy is a common obstetrical procedure with both benefits and risks. It has been associated with a 60–120 min reduction in labour duration and in the use of oxytocin, mainly in nulliparae, with no evidence of increased likelihood of fetal heart rate abnormalities or adverse neonatal outcomes (Fraser et al. 2005). Parity and the cervical dilatation at the time of amniotomy affected the results in certain studies (Barrett et al. 1992; Fraser et al. 1993). However, routine amniotomy has also been associated with an increase in the risk of infection, a higher risk of cord prolapse, and reduced liquor volume, which may result in cord compression (El-Hamamy and Arulkumaran 2005). The recommendation for clinical application is thus to reserve amniotomy for cases where labour is progressing slowly. Amniotomy trials have been carried out primarily in developed country settings with a technological medical model of childbirth care (Fraser et al. 2005).

Childbirth is a frequent event in Palestine, due to the high total fertility rate of 4.6 with 96.0% of births in health facilities and a rapidly increasing caesarean rate of 12.4% (PCBS 2005). Both access to services (Giacaman et al. 2005) and quality of perinatal care provided (Wick et al. 2005) are critical issues in this resource-poor environment. The reported incidence of HIV/AIDS is currently very low, and fetal/neonatal transmission is not a major concern (MOH 2002).

This study aimed to investigate the difference in the duration of labour for low-risk women between a policy of routine amniotomy in active labour vs a policy of conserving the membranes intact in a busy maternity ward where the use of epidural analgesia is very low. While duration of

labour was the primary outcome, the use of oxytocin and analgesia, the mode of delivery, and selected maternal and newborn outcomes were secondary ones.

Methods

This randomised controlled trial was carried out at Maqassed Hospital, a teaching and referral hospital in East Jerusalem, with approximately 2,500–3,000 births per year, between 4 April 2004 and 30 March 2005, after obtaining approval from the hospital ethics committee. Written consent from participating women was acquired on admission to the labour ward. In 2002, the ratio of multiparae to nulliparae was 3:1, the caesarean delivery rate was 15.3% and amniotomy was utilised in 79.0% of births. This trial's criteria for eligibility included women who had a low-risk full-term pregnancy with a single fetus in cephalic presentation in active labour with intact membranes and a normal fetal heart rate. The following high-risk categories were excluded: intrauterine growth retardation, suspected big baby (> 4.5 kg), pre-eclampsia, insulin dependent diabetes mellitus, more than one previous caesarean section and ante-partum haemorrhage.

The sample size was calculated to detect a difference of 45 min in the duration of labour between the two arms, based on the formula that detects the difference between two means (Kirkwood and Sterne 2003). This yielded a sample of 533 in each group. Simple randomisation with sealed envelopes was used. Women were stratified at randomisation into two groups: multiparae and nulliparae. Neither the health provider nor the women knew before randomisation the group or the sequence of allocation, but blinding was not possible thereafter. Special forms were

prepared for the study. The calculated sample size of the nulliparous group could not be achieved, as the trial had to be terminated after 1 year, due to budgetary constraints.

Those assigned to the intervention arms had their membranes routinely ruptured by the midwife shortly after randomisation, while the indications for amniotomy during the first stage in the control arms were limited to 2-h arrest of cervical dilatation, dystocia, or fetal monitor insertion. Oxytocin use in both groups was restricted to cases of 2-h cervical arrest or dystocia. Follow-up was carried out for the period of hospital stay, 24 h for normal birth and three days for caesarean operations.

Statistical analysis

Intention to treat analysis was used; proportions were compared using χ^2 test or Fisher's exact test. *T*-tests for independent samples were used to compare means and Mann-Whitney test to compare medians. Significance level was achieved at 0.05. Cox proportional hazards model were applied to assess the relationship between the two treatment groups in relation to the labour duration. Kaplan-Meier survival analysis was employed to estimate the probability of a woman's continuing in labour according to the length of time from randomisation. Data was analysed with SPSS 12.

Results

Figure 1 shows the study flow chart. The most common reasons for exclusion (with some women having more than

one) were: ruptured membranes at admission (25.7% of multiparae and 32.8% of nulliparae); induction of labour (14.6% of multiparae and 12.8% of nulliparae); prematurity (5.8% of multiparae and 9.0% of nulliparae); malpresentation (4.6% of multiparae and 4.8% of nulliparae); and advanced labour (8.4% of multiparae and 3.0% of nulliparae). The refusal rate among eligible women was low, with no significant difference between refusal and study cases in age, parity, education of women and their husbands, gestational age and booking at Maqassed hospital. The baseline characteristics of the participants in both arms of the two groups were similar (Table I).

Concerning compliance with the policy of conserving the membranes, amniotomy was performed during the first stage in the control arm of multiparae in 33.8% ($n=90$), with indications including cervical arrest (83.3%), dystocia (11.1%) and fetal distress (4.4%). The cervical dilatation at amniotomy was 3–5 cm for 79.9% in the intervention arm and 83.3% in the control arm. In the nulliparous group, amniotomy was applied during the first stage in the control arm in 60.2% ($n=50$). The indications were cervical arrest (80.0%), dystocia (14.0%) and fetal distress (6.0%). In 91.9% of the intervention arm and 76.0% of the control arm amniotomy was performed at 3–5 cm dilatation.

Other labour management practices that might affect the duration or mode of delivery were documented (Table II). In the multiparous group, oxytocin was used significantly more in the control than in the intervention arm (Table III). The indications for its use were cervical arrest in 94.4% of the intervention arm and in 83.5% of the

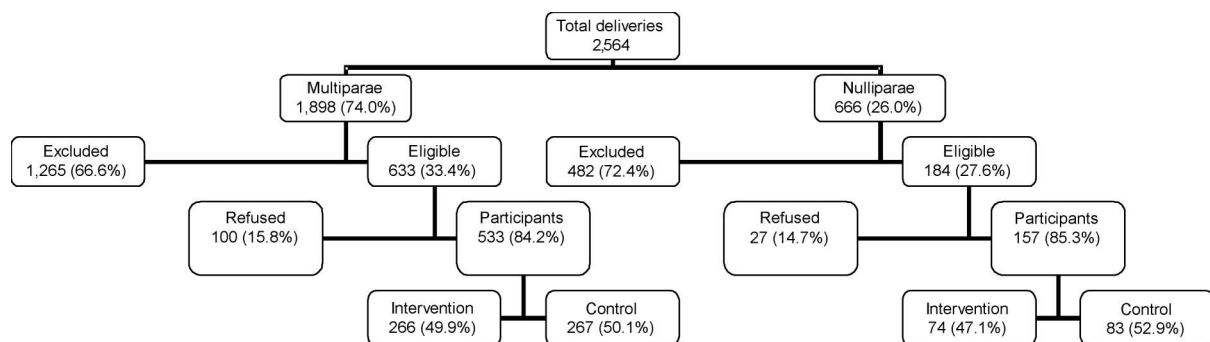


Figure 1. Flow chart of the study

Table I. Baseline characteristics of multiparae and nulliparae in the intervention and the control arms

	Multiparous women		Nulliparous women	
	Intervention	Control	Intervention	Control
Age (y) (mean \pm SD)	27.3 \pm 5.3	26.9 \pm 5.1	21.7 \pm 3.7	21.4 \pm 4.2
Education (y) (mean \pm SD)	11.0 \pm 3.2	10.9 \pm 3.2	11.5 \pm 2.8	11.6 \pm 2.9
Weight (kg)* (mean \pm SD)	72.7 \pm 12.4	74.0 \pm 11.7	75.6 \pm 10.8	73.8 \pm 10.7
Height (cm) [†] (mean \pm SD)	159.0 \pm 5.6	158.7 \pm 5.6	161.2 \pm 6.0	159.4 \pm 5.2
Employment (%)	8.3	11.3	9.5	12.0
Parity (mean \pm SD)	2.8 \pm 1.6	2.7 \pm 1.7	0	0
Gestational age (mean \pm SD)	39.1 \pm 1.1	39.3 \pm 1.1	39.4 \pm 1.1	39.5 \pm 1.0
Cervical dilatation on admission (median (25th, 75th))	3 (3,4)	3 (3,4)	3 (3,4)	4 (3,4)

*Values measured in labor room (multiparae: 206 intervention and 212 control; nulliparae: 53 intervention and 64 control).

[†]Values measured in labor room (multiparae: 195 intervention and 202 control; nulliparae: 52 intervention and 61 control).

Table II. Practices during labor and delivery in both multiparous and nulliparous groups

Practice	Multiparous group			Nulliparous group		
	Amniotomy <i>n</i> (%)	Control group <i>n</i> (%)	<i>p</i>	Amniotomy <i>n</i> (%)	Control group <i>n</i> (%)	<i>p</i>
Epidural analgesia	3 (1.2)	4 (1.5)	1.00*	7 (9.9)	3 (3.7)	0.19*
Narcotic analgesia	118 (44.5)	80 (30)	0.001	56 (76.6)	66 (79.5)	0.70
Birth companion	250 (94.7)	235 (90.0)	0.04	72 (98.6)	81 (97.6)	1.00
Eating and drinking	150 (57.0)	162 (61.8)	0.26	53 (72.6)	60 (72.3)	1.00
Bladder catheterisation	61 (23.3)	76 (29.1)	0.12	32 (45.0)	38 (46.3)	0.90
IV fluids	103 (39.0)	98 (37.7)	0.76	45 (61.6)	54 (65.1)	0.70
Shower	147 (55.7)	175 (66.5)	0.01	52 (72.2)	71 (85.5)	0.04
Exercise	106 (40.3)	133 (50.8)	0.02	45 (62.5)	52 (62.7)	1.00
Massage	57 (22.0)	74 (28.7)	0.08	25 (35.2)	29 (35.4)	1.00
Walking	174 (66.9)	205 (79.8)	0.01	50 (69.4)	66 (79.5)	0.10

*Fisher's exact test was used.

Table III. Percentages of dystocia or arrest, oxytocin use and mode of delivery

	Multiparous women				Nulliparous women			
	Intervention <i>n</i> = 266	Control <i>n</i> = 267	OR (95%CI)	<i>p</i> value	Intervention <i>n</i> = 74	Control <i>n</i> = 83	OR (95%CI)	<i>p</i> value
Dystocia/arrest (yes)	36 (13.5%)	83 (31.1%)	0.35 (0.22, 0.54)	<0.001	22 (29.7%)	50 (60.2%)	0.28 (0.14, 0.54)	<0.001
Oxytocin (yes)	36 (13.5%)	85 (31.8%)	0.34 (0.22, 0.52)	<0.001	25 (33.8%)	50 (60.2%)	0.34 (0.18, 0.65)	0.001
Mode of delivery (C/S)	4 (1.5%)	4 (1.5%)	1.00 (0.25, 4.03)	1.00	5 (6.8%)	3 (3.6%)	0.52 (0.12, 2.2)	0.48*

*Fisher's exact test was used.

control arm and dystocia in 5.6% of the intervention arm and in 14.1% of the control arm. Delay in the progress of labour (dystocia and arrest) occurred significantly more in the control arm compared with the intervention arm ($p < 0.001$).

Similar results were found among the nulliparae, where oxytocin was used significantly more in the control than in the intervention arm (Table III). The indications for its use were cervical arrest in 72.0% of the intervention arm and 84.0% of the control arm and dystocia in 16.0% of both arms. Furthermore, delay in the progress of labour (dystocia and arrest) occurred significantly more in the control arm compared to the intervention arm ($p = 0.001$). Mode of delivery was similar in both arms of the two groups (Table III). Among the multiparae, four women (1.5%) in each arm were delivered by caesarean section, three (1.2%) in the intervention arm and four (1.5%) in the control arm by instrumental delivery, while among the nulliparae, five (6.8%) in the intervention and three (3.6%) in the control arm were delivered by caesarean section, while seven (9.5%) in the intervention and 11 (13.2%) in the control arm by instrumental delivery.

The overall duration of the stages of labour is shown in Table IV. Cox's proportional hazards model (data not shown) was used to assess the relation between the two treatment arms in relation to the labour duration. Women in the intervention arm were more likely to have normal delivery after a shorter labour duration compared with women in the control arm after adjustment for other covariates including oxytocin use, pethidine use and parity. Kaplan Meier analysis curves for multiparous and nulliparous women (Figure 2) showed that the duration of labour

was shorter among multiparae than among nulliparae, and in each group it was shorter in the intervention than the control arm.

Some immediate neonatal and maternal outcomes were documented (Table V). The complication rate was generally low and there was no difference between groups in Apgar score, admission to the neonatal intensive care unit, assisted ventilation or neonatal fever or, concerning maternal findings, in the occurrence of retained placenta, postpartum haemorrhage, fever, episiotomy, or tears.

Discussion

This study was one of the first randomised controlled trials designed and carried out in Palestine. The focus on a common practice (amniotomy) during a frequent event (low-risk labour in a setting with low epidural use) attested to the relevance of the intervention, where the potential for improving the quality of care for many women and newborns is great (Alfirevic et al. 2004). Unlike some hospitals in previous studies where different obstetricians' practice style varies, the midwives and doctors at Maqassed Hospital followed standardised guidelines and models of care.

The simple randomisation method of sealed envelopes was the most appropriate given the context of no computerisation of records at Maqassed Hospital. The sample size was not calculated to detect a significant difference in the mode of delivery, and the later postpartum outcomes after discharge were not included due to impossibility of follow-up. A relatively small percentage of women were eligible for the trial (33.0% of multiparae and

Table IV. The mean \pm SD and median durations measured in minutes for different stages of the study

	Multiparous women				Nulliparous women			
	Intervention		Control		Intervention		Control	
	Mean \pm SD	Median	Mean \pm SD	Median	Mean \pm SD	Median	Mean \pm SD	Median
Enrollment–Randomisation [†]	24 \pm 31	15	23 \pm 33	15	24 \pm 38	10	25 \pm 36	14
Randomisation–ARM [†]	13 \pm 20	5	145 \pm 87	130	15 \pm 24	5	185 \pm 118	145
Randomisation–Full dilatation [†]	113 \pm 77	95*	172 \pm 106	160	231 \pm 110	210*	291 \pm 138	270
Enrollment–Full dilatation	137 \pm 82	120*	195 \pm 111	180	231 \pm 110	210*	317 \pm 136	300
Second stage of labour	9 \pm 10	5**	10 \pm 13	5	38 \pm 35	25**	39 \pm 39	25

[†]Cases randomised before active labour were excluded (13 in the multiparous group and six in the nulliparous group).

* $p < 0.001$ for the difference between the medians in the intervention and the control.

** $p = 0.6$ for the difference between the medians in the intervention and the control.

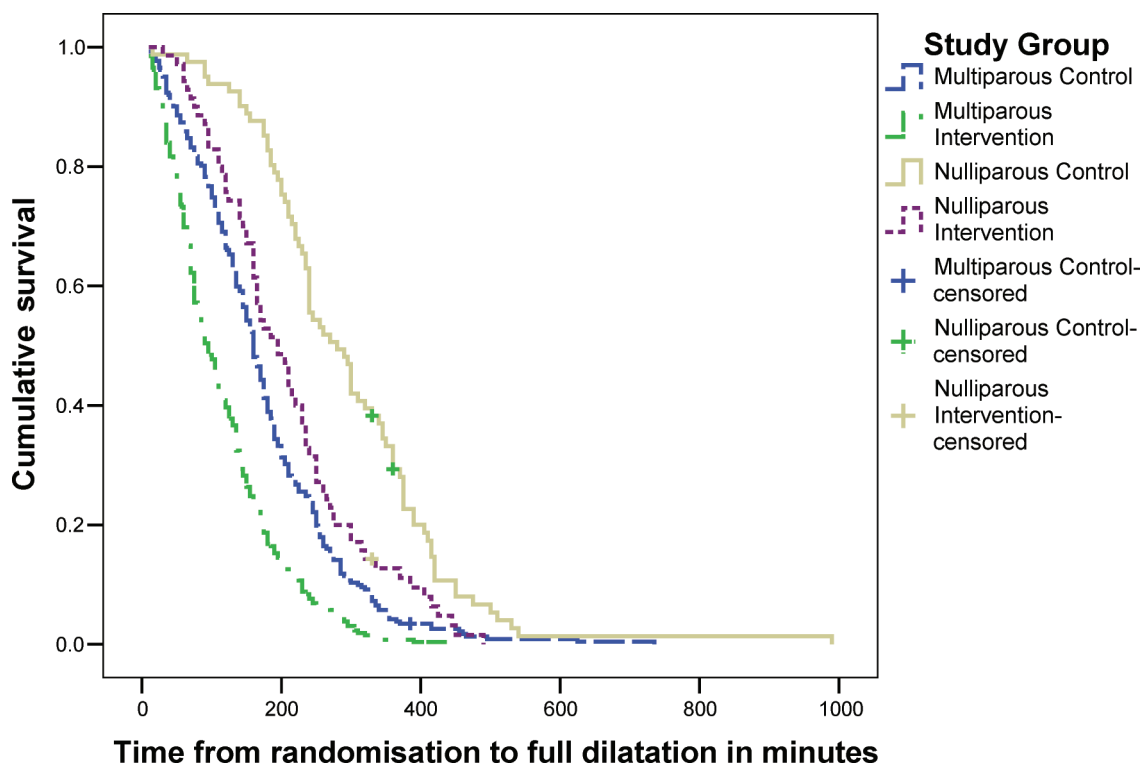


Figure 2. Kaplan–Meier curves showing the proportion of multiparae and nulliparae in the intervention and the control arms according to the time from randomisation to full dilatation

28.0% of nulliparae) due to the fact that Maqassed Hospital is a referral hospital and to the political context where very few Palestinians residing in the West Bank can get permission to enter Jerusalem to access the hospital. The refusal rate of around 15.0% in both groups was relatively low, and there was no significant difference between the refusal and the study cases in age, parity, education, gestational age, or booking.

Compliance with the policy of conserving the membranes was poor in the nulliparous group despite the established rigorous guidelines. This reflected a relatively frequent diagnosis of dystocia/arrest in labour (60.2% of nulliparae in the control), which might indicate that the existing diagnostic criteria for arrest disorders are too restrictive (Albers et al. 1996; Zhang et al. 2002).

This study showed that a policy of amniotomy early in active labour for both multiparous and nulliparous women

shortened the mean duration from randomisation to full dilatation by 58 min (95% CI 42–75 min) and 85 min (95% CI 35–116 min), respectively. These findings are generally consistent with previous studies indicating that amniotomy in early active labour resulted in a shorter duration of labour without apparent negative maternal or neonatal outcomes. Furthermore, our findings indicated that the first stage, the second stage and the overall duration of labour and birth for multiparous and nulliparous women in both arms (Table IV) was shorter in this study population than in previous studies in developed countries (Albers 1999; Albers et al. 1996; Gross et al. 2005; Nesheim 1988). The mean time from randomisation to delivery was 124 and 185 min for multiparous women (intervention and control arms, respectively) and 255 and 324 min for nulliparous women (intervention and control arms, respectively). Factors influencing the course

Table V. Selected neonatal and maternal outcomes

	Multiparous women		Nulliparous women	
	Intervention <i>n</i> (%)	Control <i>n</i> (%)	Intervention <i>n</i> (%)	Control <i>n</i> (%)
Neonatal outcomes				
Admission to NICU	3 (1.1)	4 (1.5)	0	1 (1.2)
Apgar score <7 at 1 min	9 (3.3)	8 (3.0)	5 (6.8)	5 (6.0)
Apgar score <7 at 5 min	0 (0)	1 (0.4)	0	0
Assisted ventilation	4 (1.6)	6 (2.3)	2 (2.8)	0
Neonatal fever	0	1 (0.4)	0	0
Maternal outcomes				
Post-partum haemorrhage	2 (0.7)	2 (0.7)	1 (1.4)	2 (2.4)
Maternal fever	1 (0.4)	0	0	1 (1.2)
Retained placenta	4 (1.5)	2 (0.7)	3 (4.1)	1 (1.2)
Episiotomy	8 (3.0)	14 (5.3)	54 (74.0)	59 (72.0)
Tears	77 (29.0)	90 (33.7)	11 (15.1)	19 (22.9)

of labour might have been the particular population group, the context where difficulties in movement and access are foremost in people's minds, and various components of care including midwifery support (Hodnett 2002; Langer et al. 1998), the presence of a birth companion (usually a female relative) (Madi et al. 1999), infrequent use of epidural analgesia (ACOG 2004) and permitting eating and drinking during labour (Garite et al. 2000).

The augmentation of labour with oxytocin was approximately twice as frequent in the control as in the intervention arm for both multiparae and nulliparae. This finding, also documented in other studies, is understandable, given that the control arm had more delay in the progress of labour (arrest/dystocia). Routine use of oxytocin, however, is not recommended due to the increased risk of fetal distress and death or morbidity in situations where continual monitoring cannot be guaranteed (Dujardin et al. 1995). Over one-third of all the multiparous women and over three-quarters of all of the nulliparous women had narcotic analgesia. The frequency of this practice should be reconsidered given the evidence that exists of maternal and neonatal side-effects and the long-term effects of addiction on the fetus (Caton et al. 2002; Elbourne and Wiseman 1998). Whether its frequent use is what women need and want or what birth attendants prefer needs further investigation, particularly in light of the overall short duration of labour in these findings. The use of narcotic analgesia was higher in the intervention arm of the multiparae, indicating perhaps a greater perception of pain with early amniotomy as demonstrated in other studies (Fraser et al. 1993).

The caesarean and instrumental delivery rate was very low in both groups. This low rate probably reflects multiple factors including the selection of only the low-risk cases (Garite et al. 1993), support during labour (Madi et al. 1999) and the lack of financial incentives in this hospital for operative interventions (Perkins 2004).

The prevalence of neonatal and maternal complications was low in both groups. No significant differences were found in Apgar score <7 at 1 and 5 min, assisted ventilation, neonatal fever or admission to the neonatal intensive care unit. The frequency of postpartum haemorrhage and the immediate maternal signs of infection were low in both groups and did not differ according to the policy of

membrane management. As the sociodemographic and clinical characteristics of women enrolled in this study are similar to those of other Palestinian pregnant women, it would seem that the results could be generalisable to other maternity facilities in the country.

Conclusion

This study has significant implications for clinical practice in Palestinian maternity hospitals, which exemplify the dilemma of translating evidence into practice. On the one hand, it is tempting to resort to amniotomy as a way of improving efficiency in a crowded labour ward by shortening active labour and reducing the use of oxytocin. On the other hand, and as always, the question may be asked: is it 'a valid reason to interfere with the natural process' (WHO 1999)? A difference of 1 h in the duration of labour would not appear to be, particularly given the overall short duration of childbirth found in this study. While changing providers' attitudes and practices to avoid unnecessary interventions is a difficult challenge, this option may be safer and healthier in the long run.

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