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Original Research Article

Utility of amnioinfusion in deliveries complicated by meconium stained liquor: a randomized controlled trial

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ABSTRACT

Background: Meconium stained amniotic fluid could be seen in 12-16 % of deliveries. Meconium is toxic to the newborn lung. Its presence during labour increases the risk to develop neonatal respiratory distress by about 100 times more. Meconium aspiration syndrome (MAS) occurs in about 5% of deliveries with meconium-stained amniotic fluid and death occurs in about 12% of infants with MAS. Intrapartum amnioinfusion was described as a way to dilute meconium or act as a mechanical cushioning of the umbilical cord to prevent its compression .The aim of this study is to perform a randomized controlled clinical trial to test the hypothesis that amnioinfusion can reduce the incidence of caesarean deliveries and perinatal morbidity associated with meconium stained amniotic fluid.
Methods: An interventional randomized study was conducted in Hai Jamaa hospital. 360 patients were enrolled in the study. The patients were in labour with meconium stained liquor above 37 weeks. They were randomly allocated in two groups. Group 1: amnioinfusion group and Group 2: non amnioinfusion group.
Results: Significant reduction of cesarean section rate due to fetal distress. Also significant reduction of prevalence of variable fetal heart rate decelerations, and significant reduction of incidence of MAS in patients received amnioinfusion.
Conclusions: Amnioinfusion is an easy, safe and inexpensive procedure useful in patients with meconium stained liquor.

Keywords: Amnioinfusion, Cesarean section, Fetal distress, Meconium aspiration syndrome, Meconium stained liquor

INTRODUCTION

Meconium stained amniotic fluid could be seen in 12-16% of deliveries.[1] Meconium is composed of lanugo, bile, vernix, pancreatic enzymes, desquamated epithelia, amniotic fluid, and mucus. Meconium is present in the gastrointestinal tract as early as 16 weeks' gestation but is not present in the lower descending colon until 34 weeks.[2]

Meconium is toxic to the newborn lung, leading to inflammatory reaction and epithelial injury as it descends down the respiratory tract. The pH of meconium is 7.1 to 7.2.Its acidity causes chemical pneumonitis with release of cytokines. When it is in the small airways, partial obstruction occurs, leading to trapping of air and hyper aeration. Surfactant is inactivated by the bile acids in meconium, resulting in localized atelectasis.[3]

Causes that lead to passage of meconium in utero include the normal gastrointestinal maturation or other causes related to an acute or chronic hypoxic event. Therefore meconium stained liquor maybe a sign of fetal compromise.[2]

Presence of meconium-stained amniotic fluid during labor increases the risk to develop neonatal respiratory distress by about 100 times more than those born through

clear fluid.[4] Moreover the presence meconium-stained amniotic is associated with a five-fold increase in perinatal mortality even in women who are at very low risk for obstetric complications.[5]

Meconium aspiration is the presence of meconium below vocal cord and it is seen in around 20-30 % of infants delivered through meconium-stained amniotic fluid .[3]This could happen before birth during intrauterine gasping or immediately after birth.

Meconium aspiration syndrome (MAS) is a respiratory distress that appears soon after birth, with radiographic signs of aspiration pneumonitis and presence of meconium stained amniotic fluid.[6] MAS occurs in about 5% of deliveries with meconium-stained amniotic fluid and death occurs in about 12% of infants with MAS.[7]

Several measures have been described in order to prevent such a major life threatening complication. Historically, suctioning of oropharynx and nasopharynx was done immediately after delivery of the head, before delivery of the shoulders and was initially thought to be an effective preventive measure. [8,9]

Intrapartum amnioinfusion was described by Wenstrom and Parsons as a way of diluting meconium to decrease the incidence of meconium aspiration syndrome. [10] Possible other mode of action of amnioinfusion are either mechanical cushioning of the umbilical cord to prevent its compression that may result in fetal acidaemia ,vagal stimulation and further fetal gasping and aspiration of meconium.

According to the literature, amnioinfusion was associated with a decrease in caesarean section rates and improved perinatal outcome.[11-16]

The present study was designed to test the hypothesis that amnioinfusion can reduce the incidence of caesarean deliveries and perinatal morbidity associated with meconium stained amniotic fluid.

METHODS

An interventional randomized study was conducted in Hai Jamaa hospital. 360 women were enrolled into the study during labour.

Endpoint Classification:	Safety/Efficacy
Study Intervention Model:	a 1:1 ratio by computer generated random number sequence
Masking:	sequentially numbered sealed opaque envelopes
Primary purpose:	prevention

Inclusion criteria

- ≥37 weeks of gestation,
- with a single fetus
- cephalic presentation
- Moderate or thick meconium in amniotic fluid

Exclusion criteria

- Polyhydramnios
- Previous uterine scar due to cesarean section, myomectomy or other surgeries.
- Indication for immediate delivery (cord prolapse, severe fetal bradycardia), fetal congenital anomaly, ante partum hemorrhage, maternal cardiac or pulmonary disease.
- Presence of chorioamnionitis

The primary outcome measure: was caesarean section rate.

Secondary outcome measures were:

- Decrease of heavy meconium staining
- Prevalence of variable fetal heart rate deceleration
- Meconium aspiration syndrome (which is defined as the occurrence of respiratory distress within a few hours of birth in a term baby, born through meconium stained amniotic fluid, with compatible chest X-ray findings of diffuse patchy opacifications, atelectasis, hyperinflation, air leaks).[17]
- 1 minute and 5 minute Apgar <7,
- Meconium at the level of the vocal cords,
- Hypoxic–ischemic encephalopathy as per Sarnat and Sarnat .[18]
- Admission to the neonatal intensive care unit.
- Perinatal deaths
- Maternal pyrexia

Enrollment

The study start date: November 2015. The study completion date: March 2016.

Eligible women were allocated randomly to amnioinfusion and non-amnioinfusion group on a 1:1 ratio by computer generated random number sequence. Written informed consent was taken .The samples of meconium stained fluid were obtained from each patient at rupture of the membrane. Each sample was graded according to the criteria of O'Driscoll *et al*. [19]

Group 1: amnioinfusion group

- A nasogastric tube of FG 8 was inserted trans cervical into the uterine cavity just above the head.

- Initially, 500mL of normal saline (at room temperature) was infused through the tube, over 30 minutes and then 300mL at the rate of 3mL/min

Group 2: non amnioinfusion group

The control group did not receive any amnioinfusion.

All the patients were:

1. Monitored by fetal heart tracing and uterine activity was assessed by continuous tococardiography machine.
2. Oropharyngeal suctioning was done in all newborns. All babies who were not breathing vigorously underwent tracheal suctioning. Subsequent resuscitation procedures were in accordance with the protocol for neonatal advanced life support of the American Academy of Pediatrics.[20]

RESULTS

There were no differences between the two study groups as regards demographic data and obstetric complications that predispose to meconium stained liquor and unfavorable neonatal outcomes for example IUGR, preeclampsia, oligohydraminos and post term, as shown in Table 1.

Table 1: Compression between the two groups according to demographic data.

	Group I(n = 180)	Group II(n = 180)	p
Maternal age in years			
Min. – Max.	19 – 42	18 – 43	0.593
Mean ± SD.	29.3 ± 6.9	28.9 ± 7.3	
Maternal body mass index(BMI) kg/m2			
Min. – Max.	18 – 35	19 – 34	0.295
Mean ± SD.	27.8 ± 5.2	28.2 ± 4.8	
Gestational age in weeks			
Min. – Max.	37 – 42	37 – 42	0.105
Mean ± SD.	39.1 ± 1.8	38.8 ± 1.7	
Birth weight in kilograms			
Min. – Max.	1.9 – 4.5	1.7 – 4.3	0.266
Mean ± SD.	2.8 ± 0.9	2.7 ± 0.8	
Antenatal care			
Regular	79(43.9)	83(46.1%)	0.672
Irregular	101(56.1%)	97(53.9%)	
Pregnancy complications			
Oligohydramnios	48(26.7%)	49(27.2%)	0.993
Gestational diabetes mellitus	36(20.0%)	35(19.4%)	
Preeclampsia	28(15.6%)	31(17.2%)	
Post term	50(27.8%)	48(26.7%)	
IUGR	18(10.0%)	17(9.4%)	
Labour			
Spontaneous	110	108	
Initial cervical dilatation in (cm)			
Min. – Max.	3.5 – 7.3	3 – 7	0.133
Mean ± SD.	4.3 ± 1.1	4.1 ± 1.4	
Duration between amniotomy and delivery (hours)			
Min. – Max.	3 – 12	2.5 – 11.8	0.274
Mean ± SD.	6.2 ± 2.6	5.9 ± 2.6	
Induced labour	70	72	
Initial cervical dilatation in (cm)			
Min. – Max.	0 – 4	0 – 3.9	0.147
Mean ± SD.	2.2 ± 1.4	2.4 ± 1.2	
Duration between amniotomy and delivery (hours)			
Min. – Max.	4 – 19	4.5 – 18	0.380
Mean ± SD.	10.3 ± 4.7	9.9 ± 3.9	

Table 2: Compression between the two groups according to study outcomes.

Outcome	Group I(n = 180)	Group II(n = 180)	p	OR(95%C.I)
Caesarean section rate	78(43.3%)	90(50.0%)	0.205	1.3(0.9 – 2)
Caesarean section rate due to fetal distress	50(27.8%)	78(43.3%)	0.002*	3.8(2.3 – 6.2)
Decrease of heavy meconium staining	30(16.7%)	0(0.0%)	<0.001*	-
Prevalence of variable fetal heart rate deceleration	42(23.3%)	79(43.9%)	<0.001*	2.6(1.6 – 4.1)
Meconium aspiration syndrome	10(5.6%)	23(12.8%)	0.018*	2.5(1.2 – 5.8)
Apgar <7				
One minute	15(8.3%)	29(16.1%)	0.024*	2.1(1.1 – 4.1)
Five minute	8(4.4%)	18(10.0%)	0.042*	2.4(1 – 5.6)
Meconium below the level of the vocal cords	17(9.4%)	46(25.6%)	<0.001*	3.3(1.8 – 6)
Hypoxic–ischemic encephalopathy	0(0.0%)	2(1.1%)	0.449	-
Admission to the neonatal intensive care unit	17(9.4%)	30(16.7%)	0.042*	1.9(1 – 3.6)
Perinatal deaths	0(0.0%)	2(1.1%)	0.449	-
Maternal pyrexia	9(5.0%)	8(4.4%)	0.804	0.9 (0.3 – 2.3)

*Statistically significant at p ≤0.05; OR: Odd's ratio; CI: Confidence interval

Data concerning observations describe primary and secondary outcomes were tabulated in Table 2. Statistical analysis of these data showed variable degree of differences.

As regards the cesarean section rate, there was significant reduction in cesarean section rate due to fetal distress in amnioinfusion group 50/180 than in the other group 78/180 with p=0.002 .

Also there was significant reduction of prevalence of variable fetal heart rate decelerations in group 1; 23.3% than in non amnioinfusion group 2 43.3% with p<0.001. These results could be explained by relief of cord compression by the infused fluid.

Amnioinfusion showed favorable effect on the decrease of heavy meconium30/180 while no case showed decrease in heavy meconium in group2 with p<0.001, because infused fluid lead to dilution of heavy meconium.

Other beneficial effect of amnioinfusion was observed on MAS rate. There was significant reduction of incidence of MAS in group1; 10/180 when compared to group 2; 23/180with P=0.018.Similar observations were detected as regards reduction of incidence of presence of meconium below the vocal cords in group 1 (9.4%) when compare to the non amnioinfusion group 25.6% with p<0.001.

The number of neonates with Apgar score <7 was less in amnioinfusion group than in the non amnioinfusion group with significant difference.

No case in amnioinfusion group developed hypoxic-ischemic encephalopathy while there were 2 neonates developed hypoxic-ischemic encephalopathy in group 2, which could be explained by non-availability of fetal scalp blood sampling to detect fetal acidaemia.

The most effective impact of amnioinfusion was reduction of admission to the neonatal intensive care unit in group1;9.4% while it was 16.7% in group 2with significant difference with p=0.042.

Two perinatal deaths occurred in group 2 unrelated to fetal distress. There were due to congenital heart disease detected post-partum.

Almost the same number of maternal pyrexia occurred in both groups. This observation confirms the safety of amnioinfusion on the mother.

Amnioinfusion is one of many other interventions that can reduce the risk of the meconium aspiration syndrome. Others include electronic fetal heart-rate monitoring, operative delivery in specific situations, intrauterine resuscitative procedures like maternal position and oxygenation and airway support in the newborn period. The relative benefits of amnioinfusion could depend on the pattern of use of these other interventions.

Qualitative data were described using number and percent and was compared using Chi square test or Fisher Exact test, while normally quantitative data was expressed in mean ± SD and was compared using student t-test (Table 1).

Qualitative data were described using number and percent and was compared using Chi square test (Table 2).

DISCUSSION

Amnioinfusion is considered as an applicable method for management of non-reassuring fetal heart rate changes during labor with oligohydraminos and meconium-stained liquor especially, when fetal scalp blood sampling could not be done. Theoretically increasing the amount of liquor by amnioinfusion decreases cord compression and therefore decrease the vagal stimulation, meconium passage and intrauterine gasping that leads to MAS.

The analysis of results showed no statistical differences between the two study groups as regards the demographic data as shown in table (1).This matching between the two groups resulted in omission of confounding factors that may affect the comparison between the two studied groups.

Hofmeyr et al.[21] reviewed several trials and concluded a lower frequency of MAS, cesarean deliveries, and perinatal death following amnioinfusion. These conclusions matched the results of this study.

On the other hand, Fraser et al.[16] concluded different results regarding the benefit of amnioinfusion in meconium-stained amniotic fluid.

In this study, the cesarean section rate was almost similar in the two groups, while the cesarean section rate due to fetal distress was significantly lower in amnioinfusion group than in the non amnioinfusion group. Similar results were reported by Khosla et al[22]. But different findings were reported by Hofmeyr[23], Rathor et al [24] and Mahomed et al[25] in the set ups with standard peripartum surveillance." No difference" was reported by Cialone et al[26] and Sadovsky et al[27]. Higher caesarean section rates with amnioinfusion were reported by Roger et al.[28]

In this study, the prevalence of variable fetal heart rate deceleration was significantly lower in amnioinfusion group. Similar results were reported by Surbek et al.[29] Also Puertas et al.[30] and Abdel Aleem et al [31] showed decreased frequency of variable FHR decelerations after amnioinfusion.

In this study, amnioinfusion significantly decreased the incidence of meconium at the vocal cords and similar results were reported by most of the studies in literature.[25-27,32]

The impact of amnioinfusion on Apgar scores at 1 and 5 minutes was favorable in this study which did not match with results of others' who reported non-significant improvement.[23,25,26]

The present study documented a significant decrease in the incidence of respiratory distress, MAS and admission to neonatal intensive care unit in the amnioinfusion group, the decrease in incidence of MAS in the study group must be due to decreased meconium below the level of vocal cords, decreased fetal gasping, and active resuscitation of the neonate after birth. These findings are similar to Roger et al.[28], Cialone et al[26] , Hofmeyr [23] and also The multicenter trial conducted in Zimbabwe [25] showed a statistically significant reduction in meconium aspiration syndrome in the amnioinfusion group. However Wenstrom and Parsons[10], Sadovsky et al.[27] and Uhing et al.[33] reported different results, because the low incidence of MAS in their studies.

There was no perinatal deaths in the study group, however there were two neonates died in the control group congenital heart disease.

There was no maternal mortality or major maternal complication of amnioinfusion. No case of uterine hyper tonus, in coordinate uterine activity, or amniotic fluid embolism was encountered. These results differ from those observed by Rathore et al.[24]who reported one case of in coordinate uterine activity in the amnioinfusion group and two in the control group. Abdel-Aleem et al.[31] reported uterine hyper tonus in 7.3 % cases of the amnioinfusion group as compared to 6.3 % cases of the control group who explained this decrease by dilutional effect of infused saline on bacteria that enter the uterus. Rathorea et al. also found similar results.[24]

In the present study the incidence of maternal pyrexia in the amnioinfusion group showed a non-significant decrease. While Bhatia et al[12] reported maternal pyrexia did not occur in the amnioinfusion group, but in control group, 6% cases had pyrexia.

CONCLUSION

Amnioinfusion is an applicable, easy, safe and inexpensive procedure useful in patients with meconium stained liquor. It decreased the incidence of MAS and thus, lowered the burden on overloaded neonatal care units.

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