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## Randomized Controlled Intervention Study on Effectiveness of Transcervical Intrapartum Amnioinfusion in Case of Meconium Stained Amniotic Fluid

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### ABSTRACT

One may argue that meconium is not that important. Some scientists argue that meconium has no effect on discomfort, acidity or hypoxia during fetal development. Some researchers found that meconium-stained neonates scored lower on the Apgar scale. Amniotic fluid frequently contains meconium. Obstetricians are concerned about meconium passage due to a surge in prenatal morbidity and mortality, meconium aspiration syndrome and its aftermath. To assess the effectiveness of intrapartum transcervical amnioinfusion in reducing infant morbidity and death, as well as the effect of amnioinfusion in lowering the incidence of meconium aspiration syndrome among participants with and without intrapartum amnioinfusion. The trial, which took place between March 2019 and August 2020, was a one and a half-year randomised controlled intervention study. The study was conducted at Bankura Sammilani Medical College, Bankura, in the antenatal, labor and postnatal wards of the department of obstetrics and gynecology as well as the Sncu (Sick Neonatal Care Unit). The chi-square test revealed a significant correlation ( $p = 0.022$ ) between the neonate's birth weight and the patients in the two groups. According to a t-test the new-borns of patients who did not get intrapartum amnioinfusion had a mean birth weight that was substantially lower than the newborns of patients who had it ( $t_{112} = 2.02$   $p = 0.043$ ).  $p < 0.00001$  S-Significant = 81.46. The results of the Chi-square test indicated a significant correlation between the patients in the two groups and meconium below the vocal cord ( $p < 0.0001$ ), as well as a significant correlation between meconium aspiration syndrome and the patients in the two groups ( $p < 0.0001$ ). The neonates in the amnioinfusion group needed a lot fewer SCU admissions than babies receiving standard care. Furthermore, as the frequency of maternal problems was about evenly distributed across the two groups, there was no greater incidence in the amnioinfusion group. Thus, we conclude that intrapartum transcervical amnioinfusion is a simple, risk-free and cost-effective therapy that effectively dilutes the meconium and significantly improves perinatal and maternal outcomes based on all of the previously mentioned study findings. Amnioinfusion, Meconium aspiration syndrome, Oligohydramnios and Meconium stained liquor.

## INTRODUCTION

The significance of meconium is a much debated topic. Meconium has traditionally been associated with fetal hypoxia, acidosis or distress however, some scientists dispute this notion, contending that meconium does not always signal persistent or impending fetal damage. Some researchers have found a lower Apgar score in neonates stained with meconium<sup>[1]</sup>. Meconium is frequently discovered in amniotic fluid. Obstetricians continue to be concerned about meconium passage since it is associated with meconium aspiration syndrome and its consequences, in addition to higher rates of prenatal morbidity and death.

Amniotic fluid tinged with meconium is found in 1.5-18% of cases overall<sup>[2]</sup>. The fact that the fetus secretes meconium in response to hypoxia is thought to signify fetal compromise, according to a number of ideas. Alternatively the passage of meconium in pregnancy may signify the correct maturation of the gastrointestinal system under brain control. Mesconium passage can also be caused by vagal activation following a common but transient umbilical cord entrapment<sup>[3]</sup>. From 1.7-35.8% of births are complicated with meconium aspiration syndrome<sup>[4-7]</sup>. Meconium aspiration during intrauterine gasping or at the time of first breath is thought to be the cause of meconium aspiration syndrome. It has been demonstrated that tracheal aspiration and preventive pharyngeal suctioning lower the incidence of meconium aspiration syndrome<sup>[5]</sup>.

A technique called amnioinfusion or transcervical saline infusion into the amniotic cavity, has been suggested to lower the risk of meconium aspiration syndrome. Dilution of meconium to lessen its chemical, mechanical and nonspecific inflammatory effects, as well as cushioning of the umbilical cord to address recurrent umbilical cord compression that causes fetal acidemia, are some of the possible strategies. Amnioinfusion was described by Miyazaki and Taylor in 1983<sup>[8]</sup>. They demonstrated that amnioinfusion dramatically lowers the frequency of caesarean sections and the number of fetal heart rate decelerations in the presence of meconium-stained amniotic fluid. Meconium aspiration syndrome (MAS) incidence in surgical or instrumental births as well as perinatal morbidity and death were reported to be generally lower in the patient group receiving amnioinfusion, according to several studies<sup>[7]</sup>.

Nevertheless, subsequent multicentric trials revealed that amnioinfusion did not lower the incidence of moderate or severe meconium aspiration syndrome, perinatal death or other serious diseases affecting mothers or newborns in labor with heavy meconium staining of amniotic fluid<sup>[9]</sup>. The American College of Obstetrics and Gynecology or ACOG, has

advised against using intrapartum amnioinfusion in light of these contradictory data. Instead, the procedure should only be used when meconium is present in amniotic fluid and varied decelerations in cardiotocography are present<sup>[10]</sup>. Keeping in mind the aforementioned details, this study was designed to assess the importance of meconium staining during labor and determine the impact of amnioinfusion on fetal outcome in a peripherally located tertiary medical college in Eastern India that sees about 23,000 (twenty-three thousand) births annually.

## RESULT

Chi-square ( $c^2$ ) test showed that there was no significant association between reporting institute and the patients of the two groups ( $p = 0.57$ ). Thus the patients of the two groups were comparable for reporting institute.

### Gravidity:

$c^2 = 0.56$   $p = 0.45$  NS-Not Significant

Chi-square ( $c^2$ ) test showed that there was no significant association between gravidity and the patients of the two groups ( $p = 0.45$ ). Thus the patients of the two groups were comparable for association between gravidity and the patients of the two groups.

### Risk factors:

$c^2 = 3.94$   $p = 0.26$  NS-Not Significant

Chi-square ( $c^2$ ) test showed that there was no significant association between risk factors and the patients of the two groups ( $p = 0.26$ ).

### Birth weight of the neonates (in kg):

$c^2 = 5.21$   $p = 0.022$  S-Significant

Chi-square ( $c^2$ ) test showed that there was significant association between birth weight of neonates and the patients of the two groups ( $p = 0.022$ ). T-test showed that the mean birth weight of the neonates of the patients without intrapartum amnioinfusion was significantly lower than that of the patients with intrapartum amnioinfusion ( $t_{112} = 2.02$   $p = 0.043$ ).

### Meconium below vocal cord:

$c^2 = 81.46$   $p < 0.00001$  S-Significant

Chi-square ( $c^2$ ) test showed that there was significant association between meconium below vocal cord and the patients of the two groups ( $p < 0.0001$ ).

Table 1: Association between groups with all parameter

	Without intrapartum amnioinfusion (n = 57)	With intrapartum amnioinfusion (n = 57)	Total
<b>Reporting institute</b>			
Institutional cases	25(43.9%)	28(49.1%)	53
Referral cases	32(56.1%)	29(50.9%)	61
Total	57	57	114
<b>Gravidity</b>			
Primi	30(52.6%)	26(45.6%)	56
Multi	27(47.4%)	31(54.4%)	58
<b>Risk factors</b>			
PIH	11(19.3%)	7(12.3%)	18
Post CS	5(8.8%)	5(8.8%)	10
Post dated	16(28.1%)	10(17.5%)	26
Nil	25(43.9%)	35(61.4%)	60
Total	57	57	114
<b>Birth weight of the neonates (in kg)</b>			
LBW	11(19.3%)	3(5.3%)	14
Normal	46(80.7%)	54(94.7%)	100
Total	57	57	114
Mean±Sd	2.90±0.47	3.05±0.40	
Median	2.8	3.1	
Range	2.1-3.9	2.3-3.8	
<b>Meconium below vocal cord</b>			
Yes	55(96.5%)	7(12.3%)	62
No	2(3.5%)	50(87.7%)	52
Total	57	57	114
<b>Meconium aspiration syndrome</b>			
Yes	25(43.9%)	2(3.5%)	27
No	32(56.1%)	55(96.5%)	87
Total	57	57	114
<b>SNCU admission</b>			
Yes	28(49.1%)	4(7.0%)	32
No	29(50.9%)	53(93.0%)	82
Total	57	57	114
<b>Respiratory distress</b>			
Yes	12(21.1%)	9(15.8%)	21
No	45(78.9%)	48(84.2%)	93
<b>Perinatal death</b>			
Yes	6(10.5%)	0(0.0%)	6
No	51(89.5%)	57(100.0%)	108
<b>Puerperal pyrexia</b>			
Yes	1(1.8%)	1(1.8%)	2
No	56(98.2%)	56(98.2%)	112

$\chi^2 = 0.31$  p = 0.57 NS-Not Significant

#### Meconium aspiration syndrome:

$\chi^2 = 25.67$  p<0.00001 S-Significant

Chi-square ( $\chi^2$ ) test showed that there was significant association between-meconium aspiration syndrome and the patients of the two groups (p<0.0001).

#### SNCU admission:

$\chi^2 = 25.02$  p<0.00001 S-Significant

Chi-square ( $\chi^2$ ) test showed that there was significant association between SNCU and the patients of the two groups (p<0.0001).

#### Respiratory distress:

$\chi^2 = 0.52$  p = 0.46 NS-Not Significant

Chi-square ( $\chi^2$ ) test showed that there was no significant association between respiratory distress and the patients of the two groups (p = 0.46). However,

proportion of respiratory distress among the patients without intrapartum amnioinfusion (21.1%) was higher than that of the patients with intrapartum amnioinfusion (15.8%) but it was not significant (Z = 0.91 p = 0.36)

**Perinatal death:** Since one of the cell frequencies was zero Chi-square ( $\chi^2$ ) test could not be applied, however, Fisher exact test showed that proportion of perinatal death among the patients without intrapartum amnioinfusion (10.51%) was significantly higher than that of the patientswith intrapartum amnioinfusion (0.0%) (p = 0.013).

#### Puerperal pyrexia:

$\chi^2 = 0.01$  p = 0.99 NS-Not Significant

Chi-square ( $\chi^2$ ) test showed that there was no significant association between puerperal pyrexia and the patients of the two groups (p = 0.99). None of the patients of the two groups had hypertonic uterus, scar rupture and maternal death.

## DISCUSSION

Every year, 23,000 deliveries are made at the tertiary medical college Bankura Sammilani Medical College in Eastern India, which is situated in a remote area. Meconium-stained amniotic fluid was found in five to six out of every sixty deliveries that occurred in the labor room, Department of G and O, BSMCH, on average, according to the records. 114 patients who satisfied the study's selection criteria and had meconium stained beverages were chosen at random and placed in one of two groups. Currently, amnioinfusion was administered to the trial group, which consisted of 57 patients, whereas the control group, which also included the same patients, only received conventional therapy. These days the two patient groups were evaluated using several metrics related to the outcomes for mothers and newborns.

Although intrapartum amnioinfusion has been around for over 20 years, there aren't many accounts of its routine use in developing countries. This happens because there are no tools or intrauterine catheters designed specifically for electronic fetal monitoring. The findings of this study suggest that amnioinfusion is a procedure that may be used safely, realistically and affordably in a rural context where most patients have a lower socioeconomic position. The research and control group's baseline obstetric characteristics and sociodemographic variables were equal because the participants shared similar origins and lived in the same area.

There was no statistically significant difference observed between the study group and the control group with respect to age, parity, gestational age, pregnancy-induced hypertension, postdated pregnancy, post-CS, cervical dilatation or baby sex. James 11(1994) highlights that the incidence of MSAF rises with gestational age, reaching roughly 30% at 40 weeks and 50% at 42 weeks. In their investigation, a high incidence of MSAF was observed in pregnancies at high risk. In a similar vein, our research showed that postdated pregnancy and PIH had higher incidence of MSAF.

Sandhu *et al.*<sup>[12]</sup>. The age range of 21-30 years old accounted for the bulk (80%) of cases of MSAF. Approximately 73% of MSAF cases in our study fall into the same age range. Regarding the baby's sex, there was no discernible difference between the study group and the control group. There was a substantial ( $p > 0.05$ ) variation in the babies' birth weights between the two groups. The neonates of the patients who did not get intrapartum amnioinfusion had a mean birth weight that was substantially lower than the neonates of the patients who received it ( $t_{112} = 2.02$   $p = 0.043$ ) according to a t-test. This discovery was unintentional. Incidence of low apgar score (Apgar score  $< 7$  at 1 min) in control and study group in different studies. Number

of cases with Apgar score @1min,  $< 7$  were 21.1% in study group as compared to 50.9% in control group. There was significant improvement in Apgar score@ 1 min ( $p < 0.0001$ ) in amnioinfusion group, suggesting a lesser need for immediate neonatal intervention, for which equipments and trained personnel are often lacking in developing countries. The result in present study are in accordance with the observations made by CRAMP-1 study Gupta *et al.*<sup>[13]</sup>. In this study number of cases with Apgar score @5 min,  $< 7$  were 50.9% in control group as compared to 1.8% in study group. In our study there was significant improvement in 5 min Apgar ( $p < 0.0001$ ). This study correlates with Asnani *et al.*<sup>[14]</sup> meta analysis study which shows significant reduction in incidence of 5 min Apgar  $< 7$ .

In Our study, Meconium below vocal cords was evident in only 12.3% patients receiving amnioinfusion, compared to 96.5% in the non-infusion group and there was significant association between two groups ( $p < 0.0001$ ). Similarly (20% vs. 29%,  $p < 0.05$ ) Wenstrom *et al.*<sup>[15]</sup> (20% vs 45.71%  $p < 0.05$ ) studies correlated with the present study.

Rate of Meconium Aspiration Syndrome in Control and study group subjects in different studies. In present study the incidence of Meconium aspiration syndrome was higher in noninfusion group in comparison to study group (25 vs. 2, 43.9% vs. 3.5%) and it was statistically significant. Sood *et al.*<sup>[16]</sup> (20% vs. 6.3%,  $p < 0.05$ ) Choudhary *et al.* 57 (15.8% vs. 0.7%,  $p < 0.05$ ) Bansal *et al.* 58 (9.47% vs. 2.1%) concluded the same result. A study by Asnani *et al.* 60 revealed that rate of meconium aspiration syndrome was 30% in control group in comparison to 10% in study group, thus showing significant difference between two groups ( $p = 0.025$ ) which correlated with the present study.

Rate of Sncu admission in control and study group subjects in different studies. In present study the proportion of Sncu admission was significantly higher in noninfusion group (49.1%) in comparison to amnioinfusion group (7%) ( $p < 0.0001$ ). Gupta *et al.*<sup>[13]</sup> showed that sncu admission was significantly lower in amnioinfusion group (57.14% vs. 25.71%) and a study conducted by Mohamed Farag Sherbeny<sup>[17]</sup> reported that neonates of amnioinfusion group had lesser Nicu admission compared with the noninfusion group (18.2% vs. 6.8%,  $p = 0.043$ ) which correlated with the present study.

In a randomized study conducted by Bansal *et al.*<sup>[18]</sup> reported that respiratory distress of the neonate was significantly less common in the amnioinfusion group than in the routine care group (4% vs. 12%  $p = 0.0349$ ). Similarly in present study, proportion of respiratory distress among the patients without intrapartum amnioinfusion (21.1%) was higher than that of the patients with intrapartum

amnioinfusion (15.8%) but it was not significant ( $Z = 0.91$   $p = 0.36$ ).

In present study, Perinatal mortality in amnioinfusion group was nil in comparison with the control group (10.5%). However, Fisher exact test showed that proportion of perinatal death among the patients without intrapartum amnioinfusion (10.51%) was significantly higher than that of the patients with intrapartum amnioinfusion (0.0%) ( $p = 0.013$ ). Study conducted by Asnani *et al.*<sup>[14]</sup>. The rate of mortality was two times higher in control group as compared to study group, 5% vs. 2.5%) and Gupta *et al.*<sup>[13]</sup>. There was no perinatal death in the study group but 2 deaths in the control group due to MAS, 5.7%) correlated with the present study.

In our study, complications in both Amnioinfusion and study group were same. There was no increased incidence of fever/endometritis because of the procedure. Similarly Wenstrom *et al.*<sup>[19]</sup> stated that neither the method nor the number of infusions performed appears to significantly increase in maternal complication because of the procedure.

The findings in present study highlighted the role of amnioinfusion in improving neonatal Apgar, reducing respiratory distress leading to lesser need of neonatal resuscitative measures and reduce neonatal morbidity. These findings are encouraging and providing evidence that even in well-equipped facilities amnioinfusion plays an important role in reducing neonatal morbidity. Further studies on larger sample size are recommended to elucidate and clarify the role of amnioinfusion on trends obtained in present study.

## CONCLUSION

When compared to the group receiving usual care, the amnioinfusion group's Apgar scores at 1 and 5 minutes showed a considerable improvement. Compared to the usual care group, the amnioinfusion group's neonates had a considerably decreased incidence of meconium below the vocal cord. Compared to the normal care group the neonatal amnioinfusion group had a considerably decreased incidence of meconium aspiration syndrome. Compared to the newborns in the standard care group, those in the amnioinfusion group required a considerably lower number of SCU admissions. Compared to the standard care group, there was a reduced incidence of respiratory distress in the amnioinfusion group. Amnioinfusion group perinatal mortality was lower than that of regular care group. Maternal complications were roughly evenly distributed across the two groups, therefore there was no higher frequency of them in the amnioinfusion group. Therefore, based on all of the aforementioned study findings, we draw the conclusion that intrapartum transcervical amnioinfusion is a

straightforward, risk-free and reasonably priced therapy that successfully dilutes the meconium and considerably improves perinatal and maternal outcomes.

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