**Amniotic Fluid Sludge in the Presence of Cervical Cerclage is Associated with Poor Obstetric Outcomes**

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**ABSTRACT:**

Objective: To determine if the ultrasound finding of amniotic fluid sludge in patients with cervical cerclage is associated with adverse pregnancy outcome.

Materials and Methods: Retrospective review of patients receiving cervical cerclage at one institution over a five year period. Maternal demographics, operative cerclage details, obstetric and neonatal outcome data were collected through chart review. Ultrasound images were retrospectively reviewed for the presence or absence of amniotic fluid sludge and cervical sonographic characteristics. Primary outcomes measured were preterm delivery < 32 weeks and composite neonatal morbidity, including grade III-IV intraventricular hemorrhage, bronchopulmonary dysplasia, respiratory distress syndrome, necrotizing enterocolitis, culture proven sepsis and death.

Results: A total of 105 patients were included in the study. Of those, 66 had sonographic evidence of sludge and 39 did not. Delivery at <32 weeks (34.8% vs 5.1%, p<0.0001) and <28 weeks (29% vs 5.1%, p=0.005) was significantly increased in the sludge present group vs the sludge absent group. Composite neonatal morbidity in the sludge present group trended toward but did not reach statistical significance (p=0.056). The interval from cerclage to delivery was significantly less in the sludge present group (114.6 +/- 56.1 days) compared to the sludge absent group (148.4 +/- 32 days, p=0.0008). Gestational age at delivery was significantly less in the sludge present group compared to the sludge absent group (33.3 +/- 6.7 weeks vs. 36.9+/-3.3 weeks; p=0.0025).

Conclusion: In women undergoing cerclage placement, the presence of amniotic fluid sludge increases the risk for delivery at less than 32 weeks.

Key Words: Cerclage, Neonatal outcome, Preterm Delivery, Amniotic Fluid Sludge

**Introduction:**

Amniotic fluid (AF) sludge is a powerful sonographic marker of an intraamniotic infection-related inflammatory process.1,2 It is associated with early preterm delivery, possible microbiological invasion of the amniotic cavity, and histological chorioamnionitis in both symptomatic and asymptomatic patients.[[1]](#endnote-1)1,3 Recently Romero et al, directly sampled AF sludge from a pregnant patient in preterm labor, and found it to consist of a polymicrobial biofilm.4 Sonographically, it is free floating hyperechogenic material within the amniotic fluid in close proximity to the internal cervical os.1,2 The appearance of sludge is quite different from other sonographically visualized debris within the amniotic cavity and can be distinguished from vernix or meconium.5

AF sludge has been noted in asymptomatic patients who go on to deliver prematurely as well as those with cervical cerclage.3,[[2]](#endnote-2)6 There is little data with regards to the impact of the presence of AF sludge in pregnancies treated with cerclage. The primary objective of this study was to determine if the prenatal ultrasound finding of AF sludge in patients with cervical cerclage is associated with adverse pregnancy outcome. In addition, we sought to compare specific pregnancy and neonatal outcomes among women with cerclage who did and did not have AF sludge present, including interval from cerclage placement to delivery, gestational age at delivery, birthweight, rate of preterm premature rupture of membranes (PPROM), mode of delivery, placental pathology, method of cerclage placement and cervical length measurement characteristics.

**Materials and Methods:**

A retrospective review of patients who received a cervical cerclage during pregnancy and delivered at a single institution was performed over a 5 year period from 1/1/2003 to 6/30/2008. Patients undergoing cerclage were identified using ICD-9 codes. Women carrying a singleton who underwent cerclage placement between 13 and 24 weeks with follow-up delivery and neonatal data were eligible for inclusion. Our protocol included all patients who receive cerclage to be followed with serial transvaginal sonography. Exclusion criteria included multiple gestations, patients with congenital uterine anomalies, patients lost to follow up, patients who had a cerclage but were delivered earlier because of maternal indications, those that failed an initial cerclage and underwent subsequent cerclage placement and maternal age <18 years.

All maternal charts, operative reports, neonatal charts, and transvaginal ultrasound images were reviewed by a single examiner. Maternal demographics included age, weight and body mass index (BMI) at delivery, race, multiparity, insurance payor, history of prior preterm birth, history of midtrimester birth, and history of prior cerclage. Multiparity was defined as any prior delivery and midtrimester delivery was defined as the delivery of a nonanomalous fetus between 16-28 weeks in the absence of painful uterine contractions or labor.

Sonographic images were obtained over 5 years using Philips ATL (Bothell, WA) machines from January 2003 through September 2005 and GE Voluson 730 (GE Healthcare, Milwaukee, WI) machines from September 2005 through June 2008. Sonographic images were reviewed from digital archives using Viewpoint software (GE Healthcare, Milwaukee, WI)). The data obtained from sonographic image review include: presence or absence of sludge and presence or absence of funnel. Funnel was defined as prolapse of the amniotic membranes into the endocervical canal ( >25% of the total cervical length).7 Additional measurements seen in Figure 1 included distal cervical length ratio, proximal cervical ratio, distal cervical length and total cervical length.

Data regarding cerclage placement included gestational age at placement, type of suture and technique (McDonald vs Shirodkar) used. The clinical indication for cerclage placement is defined as either prophylactic based upon history, or emergent because of documented cervical dilation on physical examination or cervical shortening noted by ultrasound. Delivery outcomes collected included delivery at <28, <32 and <37 weeks, interval from cerclage to delivery, preterm PROM rate, latency after preterm PROM, mode of delivery, and placental pathology documenting chorioamnionitis or funisitis by routine pathologic exam.

Neonatal outcome data collected included gestational age at delivery, birth weight, Apgars at 1 and 5 minutes, cord gas measurements, admission to neonatal intensive care unit (NICU), length of NICU stay, culture proven sepsis, grade III-IV intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), respiratory distress syndrome (RDS) or bronchopulmonary dysplasia (BPD), and neonatal death. Composite neonatal morbidity was defined as grade III-IV IVH, NEC, RDS and BPD, culture proven sepsis, and death.

The primary outcomes investigated were preterm delivery <32 weeks and composite neonatal morbidity in the presence or absence of AF sludge. Additional outcomes investigated included gestational age at delivery, interval from cerclage to delivery, birth weight, rate of preterm PROM, mode of delivery, placental pathology, and cervical characteristics by ultrasound in the presence or absence of AF sludge. Nominal data was analyzed using Chi square or Fisher exact depending upon cell size. For ordinal data t test was used and Fisher’s exact test was used where indicated. All data analyzed with Stata software (Stata Corp, TX, USA). P<0.05 was considered statistically significant.

**Results:**

Results: A total of 147 patients received cerclage during the study period, of which 105 met criteria to be included in the study. Of those, 66 had sonographic evidence of sludge and 39 did not. Of the 66 patients that had sludge, 46 of them had sludge noted before the placement of cerclage (71%). The majority of women with no sludge present had a history of prior cerclage compared to those with sludge present (69% vs. 3%, p < 0.0001). 77% of both groups had a history of prior midtrimester loss. BMI was larger in the sludge group and approached statistical significance (p=0.051). Logistic regression analysis ruled out BMI as a possible confounder, and the primary outcome was still found to be significant (p=0.009). The remainder of the maternal demographics were similar between the two groups, Table 1.

Sonographic cervical characteristics and cerclage data are presented in Table 2. The gestational age at cerclage placement was approximately one week later in the sludge present group compared to the sludge absent group(16.9 weeks vs 15.7, p =0.043). There was no difference between the proportion of prophylactic vs emergent cerclages in either group. Surgical technique and the type of suture used were not statistically significantly different between the two groups. There was significantly more funneling in the sludge group vs no sludge group (p<0.0001). Mean total cervical length (CL-T), mean proximal cervical length and mean distal cervical length were statistically longer in the sludge absent group compared to the sludge present group (p <0.0001, p<0.0001, and p=0.0001, respectively).

Delivery outcomes are presented in Table 3. The interval from cerclage to delivery was significantly less in women with sludge compared to women with no sludge (114.6 +/- 56.1 days vs. 148.4 +/- 32 days, p =0.0008). Delivery < 32 weeks and delivery <28 weeks was also significantly more common in women with sludge compared to women with no sludge (p<0.0001 and p=0.005, respectively). Delivery < 37 weeks, rate of preterm PROM or cesarean delivery were not statistically different between the two groups. Pathologic examination of the placenta was performed in 56.4% (22/39) of the sludge absent group and in 56.1% (37/66) of the sludge present group. Pathologic evidence of chorioamnionitis was more common in the sludge present group compared to the sludge absent group (62% vs19%, p=0.002), Table 4. Of note, patients who were candidates for antenatal corticosteroids as dictated by the NIH Guidelines received them.8 There were 2 patients that did not receive the full course.

Neonatal data is presented in Table 5. Neonates in which sludge was present delivered at an earlier gestational age (33.3 +/6.7 weeks vs. 36.9+/-3.3 weeks; p=0.0025) and had lower birth weights (2291 +/-1173 vs 2846+/-760; p=0.01) than those in which sludge was absent. The composite neonatal morbidity was not different between the two groups. There were a larger proportion of neonates who had sludge in utero that were diagnosed with bronchopulmonary dysplasia/respiratory distress syndrome (18.6% vs 2.6%; p=0.007). The remainder of the neonatal morbidities were similar between the two groups.

The distal cervical length ratio was plotted against gestational age at delivery giving a correlation of 0.408 in the sludge group (Figure 2), and -0.279 in the no sludge group. There was no association in the proximal cervical length/total cervical length ratio and gestational age at delivery for either group. In the sludge group using logistic regression analysis, we found that there was a 19 fold reduction in the odds of delivering less than 37 weeks for every 1cm increase in distal cervical length (p=0.021, CI 0.045-0.774) . In the no sludge group, at < 37 weeks there was no benefit in odds reduction of preterm delivery with increasing cerclage length noted using logistic regression (p=0.086 CI 0.81-22.4).

**Discussion:**

AF sludge has previously been demonstrated to be a risk factor for preterm labor and delivery.4 The findings in our study also showed that AF sludge was associated with an increased risk of preterm delivery <28 weeks and <32 weeks in patients with a cervical cerclage compared to those without sludge present. Gestational age at delivery and birthweight were also significantly lower in the sludge present group. Despite this, composite neonatal morbidity was not statistically significantly different between the two groups.

There was no significant difference in neonatal outcomes related to cord pH, Apgar scores, NICU admission, length of NICU stay, NEC, sepsis, neonatal death, or severe IVH. However, there was significantly more BPD in the sludge group (p=0.007) and this accordingly increased the composite morbidity score to approach significance. BPD has been linked to intraamniotic infection and inflammation in previous studies9,10, but the effect of this remains questionable.11 Mycoplasma hominis and Ureaplasma urealyticum have previously been isolated from patients whose pregnancy was complicated with sludge2,3 as well as those with suspected cervical insufficiency.12  The Alabama Preterm Birth Study found that Ureaplasma and Mycoplasma infected 35% of neonates who delivered preterm between 23-32 weeks.13 Furthermore they noted that these preterm neonates were more likely to have BPD but not IVH grade III-IV, NEC, or death, similar to the results found in this study.

There was significantly more fetal demise in the sludge group (10.6% vs 0%; p=0.044), however all of these losses were the result of an intrapartum fetal demise. These occurred in pregnancies complicated by preterm PROM with a nonviable fetus that subsequently underwent labor induction (mean GA 20.8 wks, range 17-22.8 weeks). This also correlates to the decreased interval from cerclage placement to delivery in the sludge present group. As such, the finding of sludge prior to cerclage placement raises the question of benefit in this group, particularly if cerclage is indicated at a very early gestational age and viability is unable to be achieved.

Our study found that AF sludge was very strongly associated with the presence of a funnel. Furthermore in patients with AF sludge and a cerclage, increased cervical length distal to the cerclage was associated with increased gestational age at delivery, but this was not true in the absence of sludge. Clinically the difficulty has been trying to determine factors that would identify candidates to benefit from cerclage placement. Iams et al stated that funneling was an important risk factor for preterm delivery.14 This was addressed by O’Brien et al., who studied pregnancies with cerclage and divided them into two groups, funneling to the level of the cerclage stitch and no funneling. The study found that total cervical length was not correlated with gestational age at delivery, but funneling to the level of the stitch was associated with delivery at a mean gestational age of 31.3 vs 36.8 weeks.15 Another study by Rust et al postulated that cerclage could have improved outcomes if used in the presence of a funnel and a shortened cervix as opposed to shortened cervix alone.16 In our study population the patients without sludge were more likely to have a previous history of cerclage, indicating recurrent need, and no evidence of funneling. This group also had longer procedure to delivery interval and less evidence of chorioamnionitis on pathology, potentially indicating evidence of inflammation, AF sludge, plays a larger role in poor obstetric outcome than history alone.

Our study contradicts the findings of a recent retrospective study in which there was no association between AF sludge and preterm birth in women who had undergone cervical cerclage.17 Their study significantly differs from ours in study population. About 20% of the study population in that cohort had a history of preterm delivery <32 wks compared to 77% in the current study. AF sludge in their population was not associated with preterm delivery, which is an important finding. It may not be just the presence of amniotic fluid sludge that contributes to preterm delivery, but the innate immune response as well.

AF sludge has previously been obtained transvaginally from a patient delivering prematurely and found to consist of a biofilm.3 Biofilms are known to exist as an aggregate of microorganisms in which cells adhere to each other. These may exist on surfaces, such as dental biofilm, or even in liquids. Common biofilms encountered with disease states include endocarditis, gingivitis, and bacterial vaginosis. Adaptive humoral immune response may be critically important for preventing the formation of microbial biofilms.18 Treatment of extrauterine biofilms in pregnancy has not resulted in decreased preterm birth. For instance, it was observed that women with periodontal disease and bacterial vaginosis were at risk for preterm delivery. However studies evaluating this demonstrated that individual treatment of bacterial vaginosis and periodontal disease did not improve pregnancy outcomes.19,20Accordingly the presence of a biofilm may serve to identify patients that have an innate susceptibility to them.21 Our results demonstrated that the presence of amniotic fluid sludge is correlated with an increased risk of markers for inflammation on pathology given the higher diagnosis of chorioamnionitis in the sludge group on pathologic exam. This is consistent with biofilms contributing to a chronic inflammatory state. Bacterial biofilms may represent a persistent source of antigenemia, which could fuel a chronic inflammatory state.22

There are numerous studies discussing the relevance of cervical height and pregnancy outcome with mixed results. It has been demonstrated that increased distal cervical length after ultrasound indicated cerclage placement is associated with prolonged gestation in ultrasound indicated cerclages.23 Conversely, it also has been demonstrated that in history indicated cervical cerclage, there is no significant association between cervical length and preterm delivery <35 wks.24 In our study we found that increased distal cervical length after cerclage placement in the presence of sludge is associated with a significant increase in gestational age at delivery. This was reflected as both a direct measure of cervical length, and as a ratio of the entire cervical length. In the absence of sludge, increased cervical length was not correlated with increased gestational age at delivery. Logistic regression analysis revealed that in the sludge group there was a 10 fold reduction in the odds of delivering less than 32 weeks for every 1cm increase in distal cervical length (p<0.004, CI 0.0199-0.471). In the no sludge group there was no benefit in odds reduction of preterm delivery < 32 weeks with increasing cerclage length noted using logistic regression (p=0.122 CI 0.475-568). Further analysis revealed in the sludge group there was a 16 fold reduction in the odds of delivering less than 28 weeks for every 1cm increase in distal cervical length (p=0.019, CI 0.034-0.737). In the no sludge group there was no benefit in odds reduction of preterm delivery < 28 weeks with increasing cerclage length noted using logistic regression (p=0.122 CI 0.471-568). These results suggest that in the sludge group, a higher placed cerclage may benefit in prolonging gestation and this effect was seen at 28, 32, and 37 weeks, and was statistically significant. Conversely, in the no sludge group, higher placed cerclage was not associated with any benefit, as illustrated in Figure 2.

To eliminate any source of bias, we reanalyzed our data by removing the emergent cerclages from both groups, and comparing the presence of sludge versus no sludge in prophylactic cerclages only (history and ultrasound indicated). This subanalysis found that there were significantly more deliveries <32wks (p=0.007) and <28 wks (p=0.0371) in the sludge group versus no sludge group.

The impact of AF sludge on pregnancy outcomes in general needs to be studied further. A strength of this study is that it is a large cohort of patients evaluated with cerclage and available outcome data with and without AF sludge from one institution. Another strength of this study is that a single reviewer meticulously evaluated all images and was blinded to clinical outcomes until all cervical measurements were obtained. The retrospective nature of the study is an inherent weakness and may increase the false negative rate for the presence of sludge as images were not obtained prospectively intentionally evaluating for its presence. As such the commonality of AF sludge is largely unknown, as well as its absolute impact on obstetric outcomes. Further research is needed to investigate the role of sludge in the possible etiology of cervical insufficiency in patients with risk factors.

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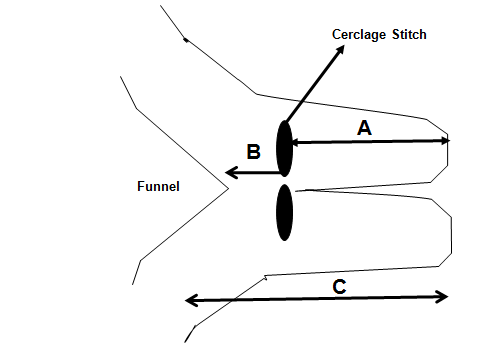
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2. **Figure 1: Cerclage Measurement Key**

   Cervical measurements (cm) obtained after cerclage placement used to derive proximal cervical ratio (B/C), and distal cervical length ratio (A/C). *A* Distance from cerclage to external os; *B* Distance from cerclage to internal os; *C* Total cervical length.*7*

   **Fig 2: Distal Cervical Length as a ratio vs Gestational Age at Delivery**

   **Table 1: Maternal Demographics**

   |  |  |  |  |
   | --- | --- | --- | --- |
   |  | Sludge Present  (n=66) | No Sludge Present  (n=39) | P Value |
   | Maternal age (years) | 29.8+-5.3 | 29.9+-5.0 | p=0.94 (NS)\* |
   | Maternal BMI (kg/m2) | 36.4 +- 8.6 | 33.4 +-5.7 | p=0.051 (NS) |
   | African American | 88% (58) | 77% (30) | p=0.141 (NS) |
   | Caucasian | 1.5% (1) | 7.7% (3) | p=0.143(NS) |
   | Other | 10.5 % (6) | 15% (6) | P=0.327 (NS) |
   | Private Insurance | 59 | 62 | p=0.805 (NS) |
   | Medicaid Insurance | 41 | 38 | p=0.805 (NS) |
   | Prior Midtrimester Delivery1 | 51/66=77% | 30/39=77% | p=0.967 (NS) |
   | Multiparous | 100 (%) | 97% | p=0.377 (NS) |
   | Prior History of Cerclage | 2/66=3% | 27/39=69% | p<0.0001 (S) |

   1Defined as Delivery of nonanomalous fetus between 16-28 weeks

   **Table 2: Cerclage and Sonographic Cervical Characteristics**

   |  |  |  |  |
   | --- | --- | --- | --- |
   |  | Sludge Present  (n=66) | No Sludge Present  (n=39) | P Value |
   | Prophylactic Cerclage (History/Ultrasound Indicated) | 43/66 (65%) | 27/39 (69%) | p=0.668 (NS) |
   | Emergent Cerclage\* | 23/66 (35%) | 12/39 (31%) | p=0.668 (NS) |
   | Gestational Age at Cerclage Placement (weeks) | 16.9 +- 3.2 | 15.7 +-2.9 | p=0.043 (S) |
   | Funnel Present | 60 (90%) | 4 (10%) | p<0.0001 (S) |
   | Mean Total Cervical Length(cm) 1 | 2.81+-1.01 | 3.94+-0.60 | p<0.0001 (S) |
   | Mean Proximal Cerclage Length 1(cm) | 1.22 +-0.88 | 2.01 +-0.61 | p<0.0001 (S) |
   | Proximal CL:Total CL Ratio | 0.503+-0.123 | 0.377+-0.024 | p=0.0006 (S) |
   | Mean Distal Cerclage Length1(cm) | 1.6+-0.39 | 1.94 +-0.46 | p=0.0001 (S) |
   | Distal CL:Total CL1 Ratio (A/C) | 0.406 +-0.095 | 0.461+-0.12 | p=0.0097 (S) |
   | McDonald Technique (%) | 97 | 95 | p=0.627(NS) |
   | Mean Sonographic Cervical Evaluation post cerclage (days) | 19.6 | 18.6 | P=0.766(NS) |
   | Shirodkar Technique (%) | 3 | 5 | p=0.627(NS) |
   | Suture used: Ethibond (%) | 33 | 51 | p=0.07 (NS) |
   | Suture used: Mersilene (%) | 67 | 49 | p=0.07 (NS) |

   **1** All Cervical Length measurements taken after placement of Cervical Cerclage

   \*Defined as membranes visible at external cervical os.

   **Table 3: Delivery Characteristics**

   |  |  |  |  |
   | --- | --- | --- | --- |
   |  | Sludge Present  (n=66) | No Sludge Present  (n=39) | P Value |
   | Interval from Cerclage to Delivery (days) | 114.6 +/-56.1 | 148.4 +/-32 | p=0.0008 (S) |
   | Vaginal Delivery(%) | 59% (39/66) | 56% (22/39) | p=0.788 (NS) |
   | Cesarean Delivery (%) | 41% (17/66) | 44% (17/39) | p=0.788 (NS) |
   | PPROM (%) | 33% (22/66) | 18% (7/39) | p=0.088 (NS) |
   | PPROM Latency(days) | 8.2+/-10.0 | 5.7+/-5.9 | p=0.729 (NS) |
   | Delivery:  <37Weeks (%) | 48% (32/66) | 31% (12/39) | p=0.075 (NS) |
   | <32 Weeks (%) | 34.8% (23/66) | 5.1% (2/39) | p<0.0001 (S) |
   | <28 Weeks (%) | 29% (19/66) | 5.1% (2/39) | p=0.005 (S) |

   **Table 4: Placental Pathology**

   |  |  |  |  |
   | --- | --- | --- | --- |
   |  | Sludge Present  (n=37) | No Sludge Present  (n=21) | P Value |
   | Chorioamnionitis by Placental Pathology (%) | 62% (23/37) | 19% (4/21) | p=0.002 (S) |
   | Funisitis by Placental Pathology (%) | 27% (10/37) | 14% (3/21) | p=0.338 (NS) |

   **Table 5: Neonatal Characteristics**

   |  |  |  |  |
   | --- | --- | --- | --- |
   |  | Sludge Present  (n=66) | No Sludge Present  (n=39) | P Value |
   | Gestational Age at Delivery (weeks) | 33.3 +/-6.7 | 36.9+/-3.3 | p=0.0025(S) |
   | Birth weight (grams) | 2291+/-1173 | 2846 +/-760 | p=0.01 (S) |
   | Intrauterine Fetal Demise (%)\* | 10.6% (7/66) | 0 | p=0.044 (S) |
   | Average Fetal Cord ph (Arterial) | 7.29 +/-0.09  (n=52) | 7.25 +/-0.10  (n=31) | p=0.07 (NS) |
   | Apgar 1 minute | 7.2 +/-2.2 | 7.8 +/- 1.7 | p=0.178 (NS) |
   | Apgar 5 minute | 8.3 +/-1.2 | 8.5 +/- 1.0 | p=0.286 (NS) |

   \*Nonviable fetus’ complicated by PROM

   **Table 6: Neonatal Outcomes**

   |  |  |  |  |
   | --- | --- | --- | --- |
   |  | Sludge Present  (n=59) | No Sludge Present  (n=39) | P Value |
   | Average GA at admission to NICU (weeks) | 28.1 | 31.9 | p=0.026 (S) |
   | Admission to NICU (%) | 23.7% (14/59) | 15% (6/39) | p=0.316 (NS) |
   | Mean NICU Stay (days) | 72.9 +/-86 | 31.7 +/-28 | p=0.27 (NS) |
   | IVH (Grade III/IV) (%) | 3.4% (2/59) | 0 | p=0.516 (NS) |
   | Bronchopulmonary Dysplasia(%) | 18.6% (13/59) | 2.6% (1/39) | p=0.007 (S) |
   | Necrotizing Enterocolitis (%) | 3% (2/59) | 5.1% (2/39) | p=1.000 (NS) |
   | Culture proven sepsis (%) | 11.9% (7/59) | 5.1% (2/39) | p=0.310 (NS |
   | Neonatal Death (%) | 3.4% (2/59) | 2.6% (1/39) | p=1.000(NS) |
   | Composite (%) | 23.7% (14/59) | 7.7% (3/39) | p=0.056 (NS) |

   [↑](#endnote-ref-2)