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**Original Research Article**

# Sepsis risk calculator versus risk-based approach for antibiotics initiation in neonates at risk of early onset sepsis: a randomized controlled trial from Indian tertiary center

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## ABSTRACT

**Background:** Early onset sepsis (EOS) continues to have high morbidity and mortality with an estimated incidence of 0.3 to 0.8 per 1000 live births at >34 weeks' gestation in high resource countries. The incidence in low resource countries is higher (2.2% of all live births from DeNIS study in India). Diagnosing EOS remains a significant clinical challenge and multivariate prediction models (sepsis calculators) can help optimize the management and use of antibiotics.
**Methods:** Objective was to determine the proportion of neonates receiving antibiotics in two groups using Kaiser Permanente sepsis risk calculator (KPSRC) and Center for Disease Control (CDC) risk-based approach in neonates greater than 34 weeks' gestation, at risk of EOS. This open labelled randomized controlled trial from tertiary care center in India evaluated the proportion of neonates who were recommended antibiotics in the two group, incidence of clinical or culture positive early onset sepsis, death within 72 hours of age and agreement (kappa value) between two groups.
**Results:** Total 216 neonates at risk for EOS were enrolled to two groups by randomization to either CDC or KPSRC in a 1:1 ratio. Mean (SD) gestation and mean (SD) birth weight of enrolled neonates was 37.85±2.04 weeks and 2506.9±522.87 g respectively. KP calculator identified 5.56% neonates as eligible for antibiotics administration versus 19.44% by risk-based approach (p=0.02). Among those who did not receive antibiotics 1 neonate in KP group (0.98%) and 2 from CDC risk-based group (2.30%) (p=0.59) developed clinical sepsis and none developed culture positive sepsis. There was one death within 72 hours in KP group versus none in risk-based group (p=1.0). The agreement (kappa value) between KP calculator and risk-based approach to initiate antibiotics was 0.83.
**Conclusions:** In neonates more than 34 weeks of gestation, antibiotics use was 28.6% less using KP calculator compared to risk-based approach, without increase in culture positive sepsis or neonatal death within 72 hours of life.

**Keywords:** Neonates, Early onset sepsis, Sepsis calculator

## INTRODUCTION

Neonatal sepsis is one of the most common causes of neonatal mortality globally.[1] Neonatal sepsis is defined as clinical syndrome characterized by signs and symptoms of infection with or without bacteremia in the first month of life. It is broadly divided into two major categories based on the time of onset of symptoms, early onset sepsis and late onset sepsis.[2] Early onset sepsis is defined as occurring within 72 hours of birth most postulated to be because of vertical transmission of bacteria before or during birth. Despite the advances in neonatal medicine, early onset sepsis remains a potentially fatal condition affecting approximately 0.3- 0.8 /1000 neonates born at >34 weeks of gestation in high resource settings.[3-5] According to DeNIS study, the incidence of neonatal sepsis is 2.2% of all live births and that of culture positive sepsis is 47%.[6-8]

The diagnosis of early onset sepsis particularly is like finding a needle in a haystack. Presence of maternal risk

factors does provide a direction to the clinicians regarding the at-risk neonates, but the precise subgroup of at-risk neonates, in whom antibiotics should be initiated remains an enigma. There is a risk factor-based approach, but it lacks objective assessment of the clinical status of the neonate. Most commonly used risk factor-based approach is by Centre for Disease Control and Prevention (CDC) guidelines which were updated in 2010.[9] Maternal risk factors such as positive high vaginal swab for group B streptococcus (GBS), rupture of membranes >18 hours and presumed chorioamnionitis (maternal pyrexia of >38 $^0$C during labor), foul smelling liquor, single unclean or more than three clean vaginal examination and prolonged labor are the factors considered by these guidelines as potential factors for neonatal sepsis.

Based on the risk factors and clinical symptoms, the neonate is investigated (blood culture, complete blood count (CBC) including white blood cell, differential counts and platelet counts, C reactive protein and ESR) before commencing intravenous antibiotics.[10] Upto 15–20% of neonates born at ≥34 weeks gestation are investigated and 5–8% are treated empirically for suspected EOS, which results in substantial numbers of neonates undergoing blood tests and empirical antibiotic therapy annually leading to high rates of neonate-parent separation, parental anxiety, admission to the neonatal unit, exposure of uninfected neonates to parenteral antibiotics, and increased healthcare costs.[9,11]

In addition to increasing antimicrobial resistance, studies have shown an association between early antibiotic exposure and asthma, allergic or autoimmune disease, obesity, type 2 diabetes mellitus and inflammatory bowel disease.[12-16]

One of the alternative methods to decide initiation of antibiotics is use of an electronic risk calculator developed by Kaiser and Permanente for neonates born >34 weeks' gestation. It uses an evidence-based algorithm to provide individual EOS risk estimates. The sepsis risk calculator not only considers the maternal risk factors, but also an objective assessment of neonate's clinical status is scored, which helps in more standardized approach to consider antibiotics.

The implementation of sepsis risk calculator in Kaiser Permanente hospitals reduced antibiotic usage by 45 to 50%.[19,20]

The reported application of sepsis calculator and reduction in antibiotics usage is from high income countries. One should be cautious in extrapolating the results between the countries not only because of differences in the EOS incidence, but also in the differences in the organism profile, the clinical care, the neonatal demographic characteristics, and available resources. Noteworthy is that mortality following neonatal sepsis is also high in low- and middle-income countries. There are limited studies in low- and middle-income countries. Present study was conducted with a hypothesis that use of KPSRC would reduce investigations and antibiotic administration in neonates compared to risk-based approach of CDC guidelines.

### *Objectives*

The primary objective of the study was to determine the proportion of neonates receiving antibiotics in two groups using KPSRC and CDC guidelines in more than 34 weeks' gestation neonates with suspect early onset sepsis. The secondary objectives were to assess rate of clinical/culture positive sepsis in neonates not started on antibiotics, death within 72 hours of life and the agreement between KPSRC sepsis and CDC guidelines in more than 34 weeks' gestation neonates with suspect early onset sepsis.

## METHODS

A hospital based randomized controlled study was conducted at neonatal unit in the Department of Pediatrics of Vardhman Mahavir Medical College and associated Safdarjung hospital over a period of 18 months. All neonates born with a gestation more than 34 weeks with risk factor for sepsis were enrolled for the study. The risk factors for sepsis which were considered were presence of foul-smelling liquor, rupture of membranes of more than 24 hours, single unclean or more than 3 sterile per vaginal examination, prolonged labor (duration of first and second stage of labor more than 24 hours). We excluded the neonates with major congenital malformation and moderate to severe birth asphyxia (Apgar <6 at 5 min). Neonates were randomly assigned in a 1:1 ratio to receive KP sepsis calculator or CDC guidelines by the treating physician (junior doctor or pediatrician on call). We modified the sepsis risk calculator by including the growth of any organism in the high vaginal swab in addition to group B streptococcus. Clinical teams were always allowed to overrule the recommendation and initiate antibiotic therapy as per their discretion. Neonate was discharged from hospital based on the unit protocol. The research was conducted after getting approval from CTRI (CTRI number 2021/01/030293) and institutional ethics committee.

### *Randomization*

We used a block randomization technique. The randomization sequence was generated using www.randomiser.org by a person not involved in enrolments and neonatal management. Randomly variable even numbered blocks were developed. Allocation concealment was ensured using serially numbered, opaque sealed envelopes that contained a slip of paper with allocation group. Blinding was not possible for the primary investigators; statistician was blinded to allocation group for analysis.

### *Intervention and procedures*

The primary investigator approached the parents of the eligible neonates with risk factor for sepsis before birth or

immediately after birth and explained the study. However, consent was taken only if the neonate met the inclusion criteria. In one group, the decision to initiate antibiotic therapy was made by the treating clinical team based on risk-based approach of CDC guidelines. Other group received antibiotics based on score of KP sepsis risk calculator. The KPSRC takes into account: the essential perinatal parameters usually available at birth (gestational age, duration of rupture of membranes, highest maternal temperature in labor, group B streptococcal colonization status, intrapartum antibiotic administration and EOS incidence), and the neonatal examination and categorization of the neonate's clinical status.[17,18] The KP Calculator then offers management recommendations based on the neonate's risk score. Empirical antibiotics are indicated when the risk is >3. The neonates are followed up till 72 hour of life or before discharge whichever is later.

### *Outcome*

The primary outcome measure was the number of neonates with antibiotics administration in suspected early onset sepsis in two groups. The secondary outcomes were number of neonates with clinical or culture positive sepsis in neonates not started on antibiotics, death within 72 hours of life and agreement rate (Kappa) between two groups for antibiotics administration.

### *Sample size calculation*

Based on the study by Goel et al with an observed 74 % reduction in antibiotics administration with use of KPSRC as compared to other guidelines and considering 80% power with 5% level of significance, the sample size calculated was 101 patients in each study group.[16]

### *Statistical analysis*

The presentation of the categorical variables was done in the form of number and percentage (%). Quantitative data were presented as the means±SD and as median with 25th and 75th percentiles (interquartile range). The comparison of the variables which were quantitative in nature were analyzed using independent tests. The comparison of the variables which were qualitative in nature were analyzed using the Chi-square test or Fisher's exact test. The data entry was done in the Microsoft excel spreadsheet and the final analysis was done with the use of statistical package for social sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0. For statistical significance. P value of less than 0.05 was considered statistically significant.

## RESULTS

Of the total 219 neonates screened for eligibility, 216 neonates were randomized to the two groups (Figure 1). There was no significant difference in the gestational age, birth weight, gender, and mode of delivery among the two study groups. Mean (SD) gestation and mean (SD) birth weight of enrolled neonates was 37.85±2.04 weeks and 2506.9±522.87 g respectively (Table 1).

The primary outcome i.e., the number of neonates requiring antibiotics was significantly less in KPSRC than CDC group. It is 5.56% versus 19.44% respectively (p value=0.002) (Table 2).

There was no significant difference in clinical sepsis among the neonates who did not receive antibiotics between the two groups KPSRC and CDC. It is 0.98% versus 2.30% respectively (p value=0.595) (Table 3).

There was no significant difference in the mortality in neonates who did not receive antibiotics between the two groups (p value=1) (Table 4).

The degree of agreement between the two methods (Kappa coefficient) was 0.83 (Table 5).

**Table 1: Demographic characteristics of the study cohort (n=216).**

| Characteristics | KPSRC (n=108) | CDC (n=108) | Total | P value |
|---|---|---|---|---|
| **Gestational age (weeks)** | 37.76±2.1 | 37.94±1.98 | 37.85±2.04 | 0.512 |
| **Birthweight (grams)** | 2466.48±514.94 | 2547.32±529.98 | 2506.9±522.87 | 0.216 |
| **Mode of delivery (LSCS) (%)** | 56 (51.85) | 59 (54.63) | 115 (53.24) | 0.682 |
| **Maternal antibiotics (%)** | 89 (82.41) | 86 (79.63) | 175 (81.02) | 0.603 |
| **Extreme risk factors (%)** | 22 (20.37) | 16 (14.81) | 38 (17.59) | 0.284 |
| **Triple I positive (%)** | 2 (1.85) | 3 (2.78) | 5 (2.31) | 1 |

**Table 2: Primary outcome of requirement of antibiotics (n=216).**

| Variables | KPSRC (n=108) (%) | CDC (n=108) (%) | Total (%) | P value |
|---|---|---|---|---|
| **No requirement of antibiotics** | 102 (94.44) | 87 (80.56) | 189 (87.50) | |
| **Requirement of antibiotics** | 6 (5.56) | 21 (19.44) | 27 (12.50) | 0.002‡ |
| **Total** | 108 (100) | 108 (100) | 216 (100) | |

‡ Chi square test.

**Table 3: Comparison of neonates who developed sepsis among those who did not receive antibiotics between KPSRC and CDC.**

| Neonates not on antibiotics who developed clinical sepsis later | KPSRC (n=102) (%) | CDC (n=87) (%) | Total (%) | P value |
|---|---|---|---|---|
| **No** | 101 (99.02) | 85 (97.70) | 186 (98.41) | |
| **Yes** | 1 (0.98) | 2 (2.30) | 3 (1.59) | 0.595† |
| **Total** | 102 (100) | 87 (100) | 189 (100) | |

† Fisher's exact test.

**Table 4: Comparison of outcome among who did not receive antibiotics between KPSRC and CDC.**

| Outcome who did not receive antibiotics | KPSRC (n=102) (%) | CDC(n=87) (%) | Total (%) | P value |
|---|---|---|---|---|
| **Death** | 1 (0.98) | 0 (0) | 1 (0.53) | |
| **Discharged** | 101 (99.02) | 87 (100) | 188 (99.47) | 1† |
| **Total** | 102 (100) | 87 (100) | 189 (100) | |

† Fisher's exact test.

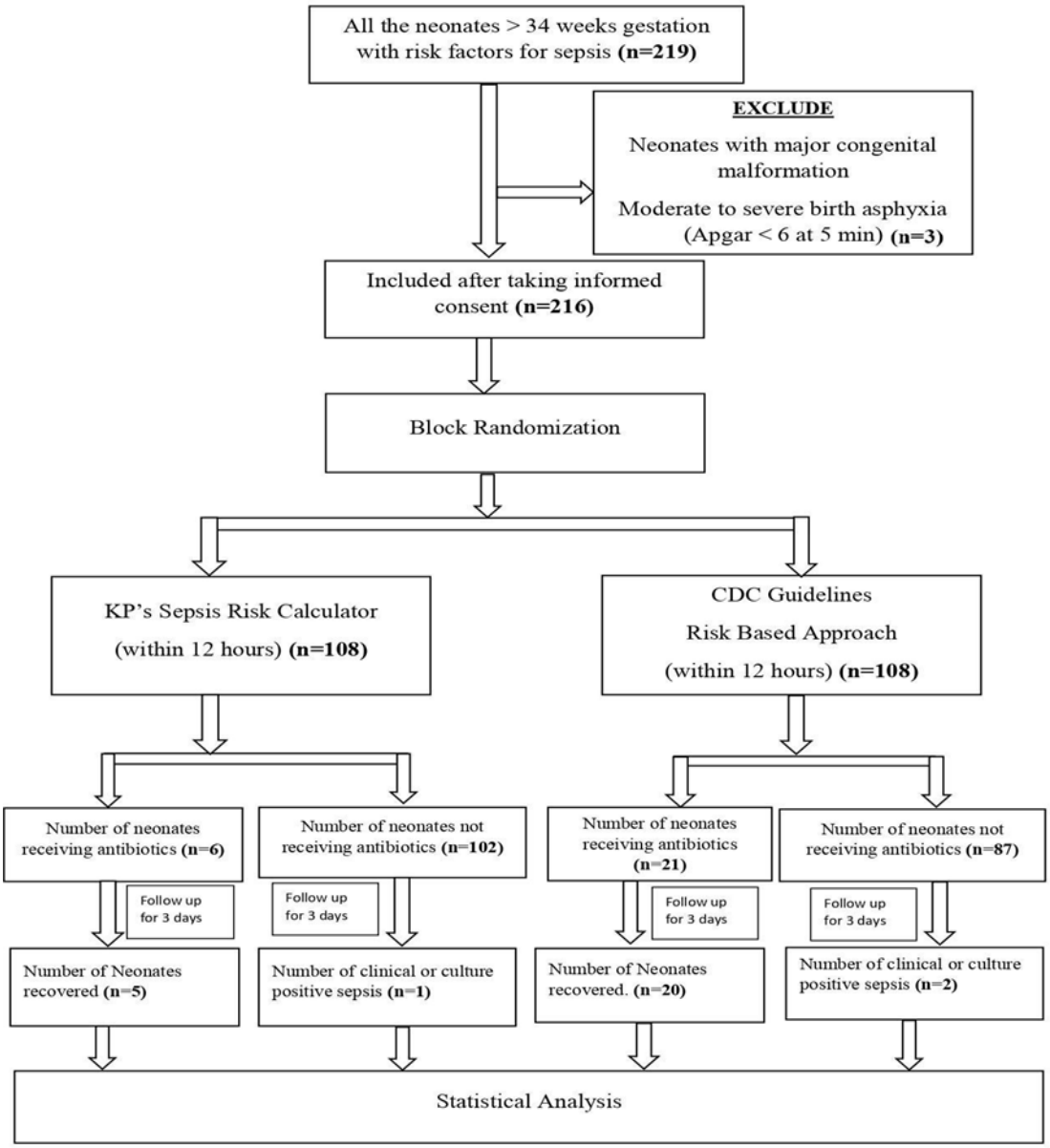


**Figure 1: Study flow.**

**Table 5: Agreement rate (kappa's coefficient) between KPSRC and CDC.**

| Variables | Antibiotics as per risk factor-based approach by KPSRC | No antibiotics as per risk factor-based approach by KPSRC | Total |
|---|---|---|---|
| **Antibiotics as per risk factor-based approach by CDC** | 11 | 36 | 47 |
| **No antibiotics as per risk factor-based approach by CDC** | 0 | 169 | 169 |
| **Total** | 11 | 205 | 216 |

## DISCUSSION

A randomized controlled study on 216 neonates compared the KPSRC with the CDC risk-based approach for initiation of antibiotics in neonates with suspected early onset sepsis. Primary outcome (number of neonates receiving antibiotics) was 6 (5.56%) versus 21 (19.44%) in KPSRC and CDC respectively. The agreement rate between KP calculator and CDC approach was found to be 0.80 in our study. To the best of our knowledge, this is the first study with randomized controlled design on comparison of two approaches for initiation of antibiotics.

Our study included only the neonates with presence of risk factor for sepsis similarly to the inclusion criteria in Huseynova et al and Strunk et al whereas the studies like Kuzniewcz et al, van Der Weijden et al, Goel et al included all the neonates born during the study period.[21-25] Sharma et al and Bridge et al included only the neonates exposed to chorioamnionitis.[26,27] Premature rupture of membranes was the most common risk factor for sepsis in our study contributing to 99.5% of our sample size. A study done by Huseynova et al[21] found 70% of sample size with premature rupture of membranes. Although the most common reported maternal risk factor for sepsis is PROM in most of the studies, the proportion of this risk factor was inordinately higher in our cohort.

The incidence of the neonatal sepsis in KPSRC was kept as 0.6/1000 by comparing the incidence of EOS in our unit in the last one year which was like the incidence reported by Van der weijden et al and Goel et al who considered an incidence of 0.5.[24,25] We have modified the maternal GBS status in the calculator. We considered maternal culture status as positive if any of the organism growth was seen in high vaginal swab.

The primary outcome measure was the proportion of neonates recommended antibiotics between KPSRC and CDC groups and it was found to be 5.56% versus 19.44% with a p value of 0.02. The reduced use of antibiotics by use of KPSRC was also reported by Goel et al with 4.3% neonates in KPSRC group and 16% neonates in NICE guidelines group received antibiotics (p value <0.0001).[25] Comparable to study, Van der Weijden et al found antibiotic use reduction from 40.8% to 11.3% between Dutch guidelines and KPSRC (p value <0.001).[24] Similarly, Kuzniewcz et al also had antibiotic administration as a primary outcome measure and found 5.0% and 2.6% before and after implementation of sepsis risk calculator.[23]

The secondary outcome measures in the present study were the number of neonates with clinical or culture positive sepsis in the neonates not started on antibiotics in two groups, and the agreement rate between KPSRC and CDC guidelines for antibiotics administration.

We noted that 2 neonates in KPSRC group and 2 neonates in CDC group needed to be started on antibiotics due to the development of symptoms within 72 hours of life out of which 1 neonate in KPSRC group developed meningitis and 2 neonates in CDC developed clinical sepsis. There were no statistically significant differences between subsequent clinical sepsis in antibiotics naïve cases between KPSRC and CDC guidelines as also observed by Strunk et al and Goel et al. [22,25]

Noteworthy is that we didn't find any culture positive sepsis in our study as also seen with Huseynova et al.[21] The possible reasons could be that these neonates were at risk of sepsis and not necessarily symptomatic for sepsis. Secondly the study was powered for detecting differences in antibiotics initiation and hence underpowered for detecting difference in subsequent culture positive sepsis.

Goel et al found seven blood culture positive EOS cases in their study.[25] One was contaminant and the neonate was well and did not receive any antibiotic. Three neonates were correctly identified by both KPSRC and NICE guidelines and were started on antibiotics just after itself and three neonates were symptomatic at later stage and were missed by both guidelines.

There were three deaths in our study. Two deaths were amongst those who were already started on antibiotics because they were symptomatic since birth. Among these two, the one in KPSRC group had a history of delayed cry at birth with meconium-stained liquor (MSL) (APGAR was 6 and 8 at 1and 5 minute respectively), started initially on antibiotics in view of severe respiratory distress and died on day 4 of life with meconium aspiration syndrome. The other neonate in CDC group was started on antibiotics in view of symptomatic in the form of feed intolerance, developed respiratory distress at 6 hour of life and got ventilated; the cause of death was sepsis (screen positive and culture negative). Third death among the neonates who were not started on antibiotics was in KPSRC group. The

neonate had a history of delayed cry at birth (Apgar 6 and 7) with a history of previous sibling neonatal death initially asymptomatic but developed seizures at 24 hours of life and started on antibiotics and mechanically ventilated. Both the sepsis screen and culture were negative, cause of death being suspected metabolic disorder. There was no statistically significant difference between the mortality between the two groups with a p value of 1.0.

The agreement value (kappa) was found to be 0.83 which suggests a strong agreement of the antibiotics received and less inter variability.

The randomized controlled study design and adequately powered for antibiotics initiation are the strengths of this study. This is the only study to report the strength of agreement between the two methods to decide initiation of antibiotics in suspected early onset disease.

However, we acknowledge the limitation that it is a single center study and was underpowered for mortality as one of adverse effect of use of lesser antibiotics. Lesser blood culture positive sepsis also limits the applicability of this study to a wider group of the population.

## CONCLUSION

To conclude, adopting the KPSRC in the management of suspected EOS in neonates more than 34 weeks of gestation, led to 28.6% lesser antibiotics use compared to risk-based approach, without increase in culture positive sepsis or neonatal death within 72 hours of life. However, larger multicentric studies, powered enough to detect the differences in culture positive sepsis and mortality as balancing measure of the reduced use of antibiotics are warranted in future.

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