

From,
Chinua Pailoor
MBBS 3rd Semester

Date: 14.10.2024

To

The Member Secretary
UGRMC
JIPMER, Puduherry

Respected Sir,

Sub: Submitting of GJ-STRAUS report to UGRMC (JIP/UGRMC/GJSTRAUS/2024/6)

I am hereby submitting my final report of the approved proposal under the GJ_SSTRAUS program 2023 along with the documents mandated by the committee.

The details of my project are as follows:

Title of the project: Association between early onset culture-proven neonatal sepsis and maternal genital colonisation - A retrospective cross-sectional study in a Tertiary healthcare centre in South India.

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Thanking you,

Yours sincerely,
Chinua Pailoor

**JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION
RESEARCH, PUDUCHERRY-605006**

(Institute of National Importance under Govt. of India)

**SUBMITTING REPORT TO JIPMER GOLDEN JUBILEE SHORT-TERM
RESEARCH AWARD FOR UNDERGRADUATE STUDENTS (GJ –STRAUS 2024)
FOR REVIEW BY JIPMER Scientific Advisory Committee (JSAC)**

1. Title:

Association between early onset culture-proven neonatal sepsis and maternal genital colonisation - A retrospective cross-sectional study in a Tertiary healthcare centre in South India

GJ STRAUS Project Number: JIP/UGRMC/GJSTRAUS/2024/6

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JIPMER Undergraduate Research Monitoring Committee (UGRMC)

GJ-STRAUS PROJECT COMPLETION CERTIFICATE

This is to certify that the Project entitled "Association between early onset culture-proven neonatal sepsis and maternal genital colonisation - A retrospective cross-sectional study in a Tertiary healthcare centre in South India" (Project number: JIP/UGRMC/GJSTRAUS/2024/6) is a bonafide work done by Chinua Pailoor of 4th semester MBBS under our/my guidance and supervision in the Department of Neonatology, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, under the GJ-STRAUS 2024 programme of UGRMC.

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REPORT

Introduction:

Sepsis and its related complications are leading causes of neonatal mortality and morbidity responsible for a quarter of neonatal deaths globally (1,2,3). In 2013, 38.9% of neonatal sepsis related deaths occurred in South Asia where neonates with culture positive sepsis had a high median case fatality rate of 34.4% (4).

Neonatal sepsis is classified by onset time into early onset (0-72 hours) and late onset (after 72 hours) (3,4). The distinction is mainly based on the probable risk factors and aetiology, with early onset acquired through vertical transmission from the mother in-utero or intrapartum, (3,5) while late onset is acquired through horizontal transmission from the hospital environment. (4)

Pathogens causing early onset neonatal sepsis (EOS) are presumed to be representative of the maternal genito-urinary tract and are associated with risk factors like maternal intra-amniotic infections, premature prelabour rupture of membranes (PPROM), but there has been an increasingly high number of EOS, which has been attributed to ultra-short horizontal transmission as well (1,3,6).

Objective:

Primary Objective:

To estimate the proportion of neonates with culture positive early onset neonatal sepsis that are associated with maternal genital colonisation.

Secondary Objective:

- a) To estimate the mortality rate in culture-proven EOS
- b) To estimate the morbidity profile of early onset neonatal sepsis caused by different bacterial pathogens which includes the following short-term outcomes:

1. Respiratory support
2. Duration of hospital stay

Methodology

This retrospective cross-sectional study focused on neonates with culture-proven early onset neonatal sepsis (EOS) admitted to the NICU of a tertiary healthcare centre in South India, between July 2022 and December 2023. The data was gathered over a period of two months. Necessary information, such as antenatal and perinatal details, clinical features, NICU course and outcomes, was retrieved from digital medical records.

The research covered neonates with sepsis occurring within 72 hours of birth, defined as a positive blood culture within the first 72 hours of life, with blood cultures done using matrix-assisted laser desorption/ionization – time of flight mass spectrometer (MALDI-TOF MS), and antimicrobial susceptibility done by VITEK. The study employed the consecutive sampling technique. The sample size was determined based on past data, with an anticipated 15% prevalence of maternal genital tract colonization in neonates with early onset sepsis, leading to a required sample size of 204. However, considering the incidence of EOS in the unit, we decided to look at data from 80 neonates collected over the past two years.

Upon approval from the Institute Ethics Committee, data on neonatal cultures and maternal swab results were obtained from the NICU Excel database, along with microbiology results. Maternal cervical swabs were routinely collected for neonates with culture-positive early onset sepsis, and these records were stored for monthly audits by the Departments of Neonatology and Obstetrics and Gynaecology. The primary outcome was assessed by determining the incidence of culture-proven maternal genital tract colonisation, with positive swab cultures.

The parameters studied included neonatal details such as gestational age, birth weight, gender, and relevant maternal risk factors (e.g., PROM, preterm labour, unclean PV examinations, and chorioamnionitis). Data on maternal comorbidities, mode of delivery and maternal swab culture results was also included. Neonatal outcomes such as APGAR scores, need for resuscitation, mode of respiratory support, symptomatology and duration of NICU stay were also recorded. The infective organism and its antibiotic resistance profile were noted, and neonatal mortality was tracked. STATA version 17.0 software was used to analyze data.

Results:

During the 18-month study period, there were 18120 livebirths and 3308 NICU admissions (Fig 1). Out of these, 79 neonates were diagnosed with culture-positive EOS, amounting to an incidence of 4.4 EOS per 1000 livebirths or 2.4 EOS cases per 100 NICU admissions. After excluding 4 neonates (due to missing data), 75 were enrolled for the study. Among the 75 neonates tested, 22 neonates were found to be infected with more than one organism. The baseline characteristics and morbidity profile are shown in tables 1 and 2.

The most commonly identified pathogens in neonatal sepsis were:

- *Escherichia coli* (n = 16)- 7 survivors (43.8%) and 12/13 (92.3%) had maternal swab growth

And 9/13 (69.2%) had concordant infection (same organism in both blood culture of neonate and swab of the mother).

- *Acinetobacter baumannii* (n = 15)- 9 survivors (60%) and 5/9 (55.6%) had maternal swab growth
- *Pseudomonas aeruginosa* (n = 14)- 5 survivors (35.7%) and 7/13 (53.8%) had maternal swab growth
- *Klebsiella pneumoniae* (n = 24)- 8 survivors (33.3%) and 9/21 (42.8%) had maternal swab growth

Maternal vaginal swab results were available for 61 patients, and 39 of these mothers (63.9%) showed evidence of genital tract colonization. In the maternal genital swabs, the most frequently isolated organism was *E. coli* (n = 26). Among the 61 maternal swab samples, 22 patients (36%) showed no colonization.

Positive maternal genital swab was seen in 19/29 (65.5%) of the survivors and 20/32 (62.5%) of the non-survivors.

The pattern of maternal genital tract colonisation was as follows. A total of 9 unique organisms were found. A total of 4 mothers had polybacterial colonisation.

- *Enterobacter cloacae*-1
- *S. agalactiae*-3
- *K. pneumoniae*-4
- *Serratia marcescens*-1
- *S. aureus*-1
- *Escherichia coli*-26
- *Candida albicans*-4
- *Enterococcus faecium*-1
- *Enterobacter hormaechei*-2

Concordant growth between maternal vaginal swabs and neonatal blood cultures was observed in 13 neonates, where the same organism was isolated from both the mother and the neonate. The organisms involved in concordant infections included:

- *E. coli* (n = 9)
- *K. pneumoniae* (n = 1)
- *Streptococcus agalactiae* (n = 2)
- *Candida albicans* (n = 1)

The mortality rate was 56% which was significantly higher than the previously reported 37.5 % in a previous study (7) and closer to the 54% reported in the study by Shane et al (8). The survivors (n=33) had an average hospital stay of 36 days. Meningitis was seen in 11/33 (33.3%) of all survivors.

Neutropenia (<1800 Neutrophils/mm³) and leukopenia (<5000 Leucocytes/mm³) were observed in 40 (53.3%) neonates. None of the identified covariates were significantly associated with mortality in univariable analysis (table 3).

Discussion:

The present study was conducted to study the maternal genital colonisation patterns in neonates with culture proven EOS. We found that colonisation was prevalent in 63.9% of mothers, whose neonates developed culture proven EOS. It is widely believed that maternal genital tract colonisation is one of the risk factors for development of early onset neonatal sepsis. A previous study conducted in Sri Lanka (10) looking at maternal genital tract colonization with selected potential pathogens of neonatal sepsis showed that 18.8% had Enterobacteriaceae colonisation. They also suggest that maternal genital tract colonisation might be an important risk factor for early onset neonatal sepsis. In a study conducted in Pakistan in 2008, the *E. coli* colonization among pre-delivery mothers has been reported as 13.7% ($n = 100$), while the colonization rate for *Klebsiella pneumoniae* was 10.5% ($n = 77$). (11) Another study conducted in Argentina in 2012 revealed 18.55% ($n = 48$) colonization rate for Enterobacteriaceae among 259 pregnant women, and the species-specific colonization rates were 14.3% ($n = 37$) for *E. coli* and 1.2% ($n = 3$) *Klebsiella pneumoniae*.

We observed that the incidence of maternal genital tract colonisation is significantly higher, 63.9% of which in mother's whose children have been diagnosed with EOS. This could be explained by the fact that we included only culture proven EOS cases, where the likelihood of maternal genital colonisation is higher. Further analysis showed that out of these 39 women, 87.2% ($n=34$) had Enterobacteriaceae colonisation. This accounts for 55.7% for whom a vaginal swab was performed. This is significantly higher than the previously reported 18.55% in Argentina or 18.8% in Sri Lanka. 21% of all neonates ($n=13$) showed concordant infections with the same organism isolated from the neonates' blood and maternal genital tract. *E. coli* was the major causative organism for such infections.

Previous studies identified Group B Streptococcus (GBS) as a major causative organism for EOS, responsible for 38-43% of all EOS cases in the US (12). The most frequent pathogens as per this study were *Escherichia coli* (86 [36.6%]) and group B streptococcus (GBS; 71 [30.2%]). Another study (13), showed that GBS (38%) and *E. coli* (24%) were the major causative organisms. In 2011, a study(14) conducted in the US showed that the incidence of GBS and *E. coli* EOS was 43% and 29% respectively. On the contrary, we found that only 5.33% had GBS (n=4) infection. The three studies mentioned above see an incidence of 24-36.6% of *E. coli* sepsis. In our study a similar finding was obtained with 21.3% (n=16) of all EOS caused by the organism. A study conducted in Serbia (7) between 2013 and 2015 revealed that *Klebsiella*, *Acinetobacter*, *Pseudomonas*, *Escherichia coli*, *Serratia*, and *Citrobacter* were most frequently identified in EOS. Our findings indicate that GBS sepsis is not the major causative organisms for EOS in this setting and contributes to a minority of the cases. Most of the infection load is caused by 4 causative organisms, *E. coli*, *P. aeruginosa*, *K. pneumoniae* and *A. baumannii*. These four organisms together make up 83.33 % (n=70) of the organisms isolated from blood cultures. Fungal sepsis was also observed with an incidence of 5.33% (n=4) with both *Candida albicans* and *Candida tropicalis* causing these infections.

A meta-analysis was conducted in China (15) where a total of 17 studies were included on major perinatal risk factors for EOS. It was revealed that perinatal asphyxia, amniotic fluid meconium contamination, GBS colonisation in pregnant women, chorioamnionitis, PROM, lower gestational age, perinatal fever, VLBW, >3 P/V examinations and maternal UTI/reproductive tract infection were major risk factors for EOS (16). Common maternal risk factors for EOS included PROM (17), chorioamnionitis, and maternal comorbidities such as gestational diabetes and hypertension. Over 50% of the neonates requiring respiratory support were born to mothers with these risk factors.

One of the objectives of this study was to find the mortality rate amongst Neonates with EOS. The overall mortality rate in this study was 56%, which is significantly higher than previously reported rates of 37.5% in similar studies (7). It was closer to the postulated 54% as per an article published in 2017 (18). A study conducted in the United States between 2005 and 2008 reported the mortality rate to be closer to 10.9% with *E. coli* (24%) and GBS (38%) being the major causative organisms. (13) This high mortality rate suggests the severity of EOS in the study population, with Gram-negative organisms being particularly fatal. The mortality rate was similar among neonates born to colonized and non-colonized mothers,

indicating that factors other than maternal colonization alone may contribute to poor outcomes.

To the best of the authors' knowledge, this is the first study to look at maternal genital tract colonisation patterns in mothers of neonates with early onset sepsis. Despite the small sample size, this study provides a holistic outlook into EOS, its epidemiology, risk factors, clinical outcome and causative organisms. Further research, particularly regarding the link between maternal genital colonisation and EOS as well as other risk factors, are essential to address the problem of high mortality and morbidity associated with neonatal sepsis in such low resource settings. Maternal genital colonization as a significant risk factor to neonatal sepsis, might be relevant in *E. coli* infections, while the same may not be true for other culture proven EOS cases. The high incidence of maternal genital tract colonisation and neonatal mortality in this study warrants more studies to be conducted on this, with a larger sample size in similar low resource settings. The major limitation of this study is its sample size of 75. Though consequential, the size was smaller than initially required. This might have limited the statistical power, resulting in the under-representation or misrepresentation of some trends. Similarly, swab results were available for 61 mothers, which could decrease the robustness of the conclusions regarding maternal colonization. The study was a single centre study, limiting the generalizability of the findings to other regions or healthcare settings.

Summary

This retrospective study looked at 75 neonates diagnosed with culture-proven early-onset neonatal sepsis (EOS) admitted to a tertiary healthcare centre in South India. The study looked into the role of maternal genital tract colonization and its association with EOS, and found that 63.9% had maternal genital colonization. The most commonly isolated organism from the maternal genital tract was *Escherichia coli* (n=26). It caused 21.3% of all EOS cases, aligning with global trends. (12-14). 17.3% of neonates (n=13) showed concordant infections where the same organism was found in both maternal and neonatal cultures. This observation reinforced the link between maternal colonization and neonatal sepsis. The study shows that maternal colonization, especially with *E. Coli*, plays a significant role in the pathogenesis of EOS.

The mortality rate was 56%, higher than the previously reported rates of around 37.5%. (7). Gram-negative bacteria (*Klebsiella pneumoniae*, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*, *Escherichia Coli*) caused most of these infections. However, *Streptococcus*

agalactiae (Group B Streptococcus), a common cause of EOS in Western countries, contributed to only a minority of the cases (5.3%). (12-14)

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Tables:

Table 1: Baseline characteristics:

Parameter	Number (N=75)	95% CI / Range
Mean GA in wk (SD)	32.6 (4.8)	24-43
Mean birthweight in g (SD)	1660 (857)	600-3880
Males	40 (53.3%)	41.4-64.9
Mode of delivery	35 (46.7%)	35.1-58.6
Maternal comorbidities	51 (68.9%)	56.2-78.3
Receipt of antibiotics for risk factors for sepsis	33 (44%)	32.5-55.9
Perinatal asphyxia (1 min APGAR <4)	23 (30.7%)	20.5-42.4
Need for resuscitation	33 (44%)	32.5-55.9
Transported on respiratory support	40 (53.3%)	41.4-64.9
PROM	40 (53.3%)	41.4-64.9
Prolonged ROM	16 (21.3%)	12.7-32.3
MSL	23 (30.7%)	20.5-42.4
Clinical chorioamnionitis	7 (9.3%)	3.8-18.3
Spontaneous onset preterm labour without PROM	9 (12%)	5.6-21.6
Maternal fever	10 (13.3%)	6.6-23.2
>3 PV examinations	39 (52%)	40.2-63.7
Steroid coverage in preterm (N=57)		
➤ Any dose	49 (86%)	74.2-93.7
➤ Full course	21 (36.8%)	24.4-50.7

Intrapartum antibiotics	34 (45.3%)	33.8-57.3
Growth in maternal high vaginal swab	61 (63.9%)	50.6-75.8
Concordant growth in maternal vaginal swab and neonatal blood culture	13 (21.3%)	11.9-33.7

Table 2: Disease severity and morbidity profile

Parameter	Number (N=75)	95% CI / Range
Mean age of symptom onset	28 (15)	6-70
Symptomatology		
➤ Respiratory distress	54 (72%)	60.4-81.8
➤ Shock	54 (72%)	60.4-81.8
➤ Apnea	25 (33.3%)	22.9-45.2
➤ Bleeding	49 (65.3%)	53.5-76.0
Mode of nutrition at symptom onset		
➤ Orogastric tube feeds	45 (60%)	48-71.1
➤ Parenteral	24 (32%)	3-16.6
➤ Oral feeds	6 (8%)	21.7-43.8
Mode of respiratory support before symptom onset		

➤ None		
➤ CPAP/ HFNC	20 (26.7%)	17.1-38.1
➤ NIV	23 (30.7%)	20.5-42.4
➤ Invasive ventilation	23 (30.7%)	20.5-42.4
	9 (12%)	5.6-21.6
Highest mode of respiratory support		
➤ None	6 (8%)	21.7-43.8
➤ CPAP/ HFNC	11 (14.7%)	7.6-24.7
➤ NIV	8 (10.7%)	4.7-19.9
➤ Invasive ventilation	50 (66.7%)	54.8-77.1
Total duration of respiratory support (median)	3	1-72
Meningitis	15 (20%)	11.6-30.8
Hydrocephalus	1 (1.3%)	0.03-7.2
Ventriculitis	1 (1.3%)	0.03-7.2
AKI	7 (9.3%)	3.8-18.3
Mortality	42 (56.0%)	44.1-67.5

Table 3: Survivors vs non-survivors

Parameter	Survivors (n=33)	Non-survivors (n=42)	P-Value	OR (95% CI)
Mean GA in wk (SD)	33.1 (4.6)	32.3 (5.0)	0.52	
Mean birthweight in g (SD)	1697 (792)	1630 (913)	0.74	
Mean age of symptom onset Median	32.4 (17)	25.2 (13)	0.04	
Males	18 (54.5%)	22 (52.3%)	0.83	0.5-2.63
Mode of delivery	VD-17 (51.5%) LSCS-15 (45.4%) Instrumental-1 (3.03%)	VD-18 (42.8%) LSCS-22 (52.3%) Instrumental-2 (4.7%)	0.43	0.61-3.10
Maternal comorbidities	22 (66%)	31 (73.8%)	0.45	0.54-4.02
Perinatal asphyxia (1 min APGAR <4)	9 (27.2%)	14 (33.3%)	0.57	1.33 (0.49-3.62)
Need for resuscitation	11 (33.3%)	22 (52.3%)	0.10	0.86-5.65
Transported on respiratory support	14 (42.4%)	26 (61.9%)	0.095	2.20 (0.87-5.58)
PROM	20 (60.6%)	20 (47.6%)	0.59	0.265 (0.23-1.48)
MSL	9 (27.7%)	14 (33.3%)	0.57	1.33 (0.49-3.62)
Clinical chorioamnionitis	4 (12.12%)	3 (7.1%)	0.47	0.557 (0.11-2.68)
Spontaneous onset preterm labour	4 (12.12%)	5 (11.9%)	0.80	1.07 (0.62-1.85)
Maternal fever	5 (15.15%)	5 (11.9%)	0.68	0.756 (0.20-2.87)
Intrapartum	12 (36.4%)	22 (52.3%)	0.39	1.28 (0.72-

antibiotics				2.30)
Growth in maternal high vaginal swab	19/29 (65.5%) 4 case sheets not available	20/32 (62.5%) 10 case sheets not available	0.40	1.33 (0.68-2.62)

Table 4:

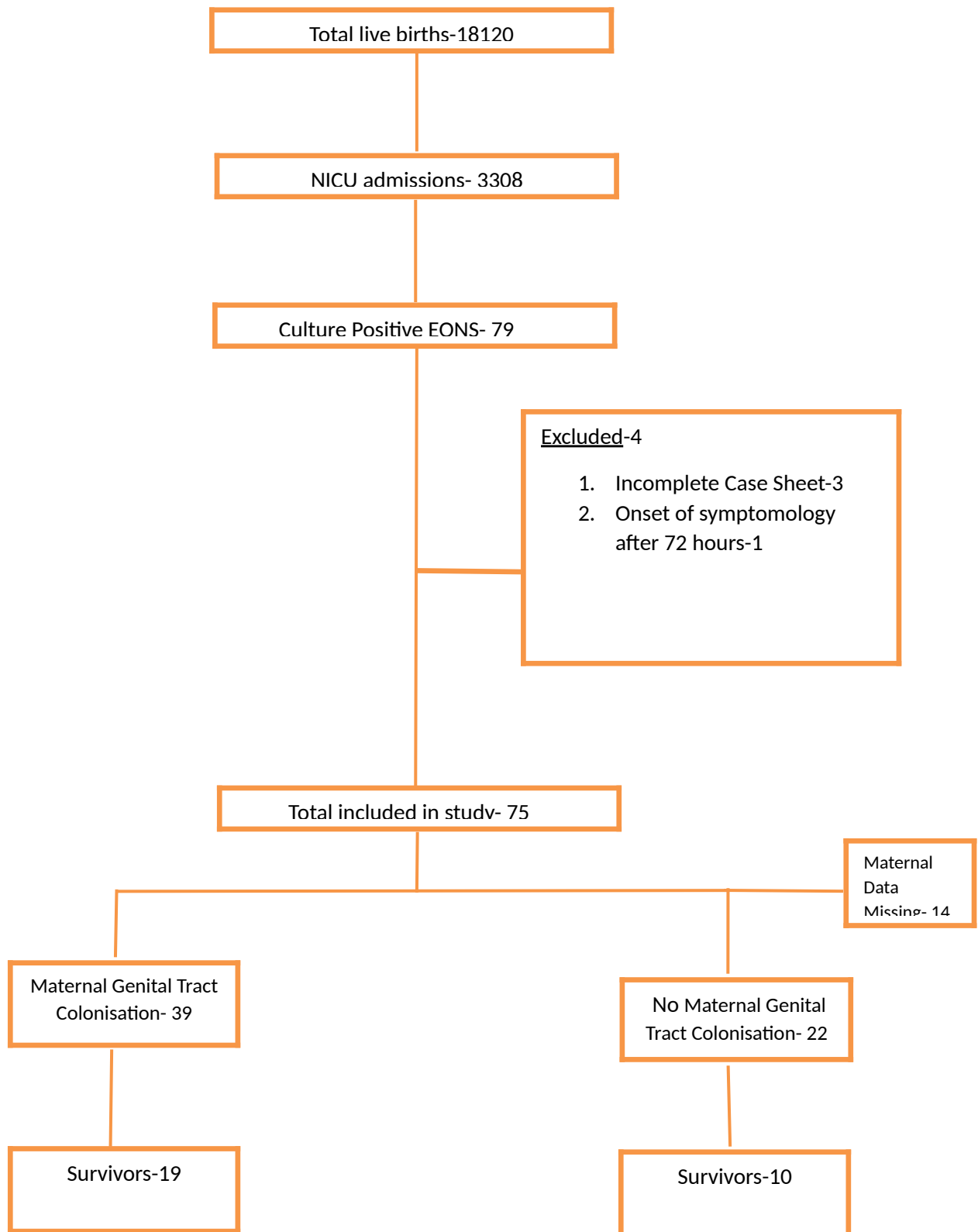
Infective Organism as per Culture report:

Infective organisms	No. of patients infected
Klebsiella pneumoniae	24
Escherichia coli	16
Acinetobacter baumannii	15
Pseudomonas aeruginosa	14
Enterococcus faecalis	6
Elizabethkingia anopheles	5
Candida albicans	3
Pseudomonas stutzeri	2
Aeromonas hydrophila	2
Micrococcus luteus	2
Candida tropicalis	1
Serratia marcescens (non-pigmented)	1
Enterococcus meningitis	1
Elizabethkingia meningoseptica	1
Acinetobacter pittii	1
Staphylococcus epidermidis	1
Micrococcus	1
Enterobacter cloacae	2
Haemophilus influenzae	1
Aeromonas punctata	1

Streptococcus agalactiae	4
N=21	N=104

*n=104>75 as some patients were infected with multiple organisms

Flow diagram



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**JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION &
RESEARCH**

(Institution of National Importance under Ministry of Health & Family Welfare, Government of India)
Dhanvantari Nagar, Puducherry – 605 006

PLAGIARISM CHECKING COMMITTEE (PCC)

CERTIFICATE

This is to certify that the manuscript submitted by Mr. Chinua Pailoor, MBBS Student, with the following details has been processed using iThenticate Software and it is acceptable for submission as a GJ STRAUS project.

Reference No: 3585

Title: Association between early onset culture-proven neonatal sepsis and maternal genital colonisation - A retrospective cross-sectional study in a Tertiary healthcare centre in South India.

Course & Year: MBBS (GJ-STRAUS Project); 2024

Guide: Dr. Murugesan A

Dr. Noyal Mariya Joseph

**MEMBER SECRETARY
PLAGIARISM CHECKING COMMITTEE
JIPMER**

Date: 14.10.2024

To

1. Candidate: Mr. Chinua Pailoor
2. Guide: Dr. Murugesan A, for information

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JIPMER Undergraduate Research Monitoring Committee (UGRMC)

Dr. Rakesh Aggarwal
Director,
JIPMER

Dr. D M Thappa
Dean (Research),
JIPMER

CERTIFICATE

This is to certify that the research project proposal with the following details **has been approved** by the **Undergraduate Research Monitoring Committee**, in the meeting of (UGRMC) held on 11.3.2024, **subject to clearance of Institute Ethics committee.**

Reg. No. of the Proposal: JIP/UGRMC/GJSTRAUS/2024/6

Title of the Proposal: Association between early onset culture-proven neonatal sepsis and maternal genital colonization - A retrospective cross sectional study in a tertiary healthcare centre in South India

Investigator : Chinua Pailoor

Guide : Dr. Murugesan A, Department of Neonatology

Dr. Nanda Kishore Maroju
Member secretary,
Undergraduate Research Monitoring Committee

Date: 24.3.24
To: Investigator, Guide



INSTITUTIONAL ETHICS COMMITTEE FOR OBSERVATIONAL STUDIES
DHR REG. NO. EC/NEW/INST/2020/331
CERTIFICATE

Date: 31/05/2024

To,
Chinua Pailoor, MBBS
Undergraduate student, JIPMER,

Ref: Your project no. JIP/IEC-OS/2024/61 entitled, "Association between early onset culture – proven neonatal sepsis and maternal genital colonisation – a retrospective cross sectional study in a tertiary healthcare centre"

Dear Chinua Pailoor,

The following documents of the above mentioned project were reviewed and approved through a full board review process:

1. Research Protocol
2. Application form requesting Waiver of Consent
3. Departmental Screening Committee approval certificate
4. CV of Guide and Co-Guide
5. Undertaking by the Guide for overall responsibility of study

It is understood that the study will be conducted under the supervision of Dr. Murugesan A, Assistant Professor, Department of Neonatology (Guide), Dr. Bhabani Pegu, Associate Professor, Department of Obstetrics & Gynecology, (Co-Guide) in a total of 80 research participants, as per the submitted protocol.

The IEC grants waiver of consent for the above mentioned study.

This approval is valid for three years, the entire duration of the project or a shorter period based on the risk whichever is less.

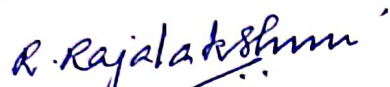
No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new

information that may affect adversely the safety of the research participants or the conduct of the research.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) **on or before 10/03/2025.**

A copy of the final report should be submitted to IEC for review.

Sincerely yours



Dr. Rajalakshmi R,

Member Secretary

IEC – Observational Studies

Date of approval of the study: 11/04/2024

**Member Secretary
Institutional Ethics Committee
(Human Studies),
JIPMER, Puducherry**