ORIGINAL ARTICLE

Prevalence and Perinatal Outcomes of Group B Streptococcus Positive Mothers in a University Hospital in Pahang, Malaysia

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ABSTRACT

INTRODUCTION: Group B *streptococcus* (GBS) is a leading cause of early neonatal infection and is related to various maternal infections. This study aims to determine the prevalence of GBS-positive mothers and their pregnancy outcomes in a University Hospital in Pahang, Malaysia. **MATERIALS AND METHODS:** A comparative cross-sectional study was conducted from October 2021-May 2022, involving 230 pregnant women between 35-38 weeks follow-up at this hospital. Rectovaginal swab (RVS), high vaginal swab (HVS), and midstream urine (MSU) cultures were sent for GBS screening in asymptomatic mother, and positive mothers received intrapartum antibiotic prophylaxis (IAP) as per protocol. Maternal outcome analysed were preterm pre-labour rupture of membrane (PPROM), preterm labour, maternal pyrexia, and puerperal infection. Whereas, neonatal outcomes include prematurity, low Apgar score, requirements of NICU/SCN admission and antibiotic; and diagnosis of neonatal early-onset GBS (EOGBS) disease. **RESULTS:** 58.6% of participants were tested GBS-positive based on either RVS, HVS, or MSU culture. There was no significant association between maternal GBS status, sociodemographic, and clinical background except for being overweight (mean BMI 26.3 kg/m^2, p= 0.047). Maternal and neonatal outcomes were not significantly different between GBS-positive and GBS-negative mothers. **CONCLUSION:** The prevalence of GBS colonisation (58.6%) was higher compared to reports worldwide. However, the implementation of GBS screening and IAP had successfully prevented the development of EOGBS disease and complication for both mothers and neonates. Therefore, screening for asymptomatic mother is important and effective for GBS infection.

Keywords
Group B Streptococcus, Prevalence, Screening, Intrapartum antibiotic prophylaxis, Perinatal outcomes

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INTRODUCTION

Streptococcus agalactiae, commonly known as Group B Streptococcus (GBS), is a facultative gram-positive microorganism. In several women, GBS is part of the natural gastrointestinal and vaginal microbiomes.[1] Gastrointestinal tract is a reservoir for GBS and source of genitourinary colonisation.[1] Despite being among natural microbiome, maternal colonisation with GBS in the genitourinary or gastrointestinal tracts is the primary risk factor for early-onset neonatal GBS (EOGBS) disease. EOGBS has been recognised as one of the leading causes of neonatal sepsis, pneumonia, and meningitis.[2]

Historically, since the 1970s, GBS has been identified as one of the major infectious cause of early neonatal morbidity and mortality in industrialised countries, leading to case-fatality rates of approximately 50%.[3] However, following the implementation of preventative measures, including the GBS screening policy and intrapartum antibiotic prophylaxis (IAP) approach, a marked decline in GBS diseases has been seen to date.[4]

It has been globally reported that the rates of maternal GBS colonisation range from 0-35%, which may differ between geographic locations.[5] When left untreated, about

50% of neonates of GBS-positive mothers will be colonised, and 1-2% will progress to EOGBS.[6]

A study by Muller et al concluded that maternal GBS colonisation during pregnancy and delivery constitutes not only a threat to neonates, but also to the mother as well. The possible complications that may affect the mother comprise peripartum infections, such as bacteraemia, sepsis, meningitis, endometritis, and caesarean or perineal wound infections.[7]

Despite these alarming outcomes brought by maternal GBS colonisation to both neonates and mothers; the information available on the colonisation rate and perinatal outcomes are still limited in most Asian nations, including Malaysia. In addition, the evaluation of current preventive measures taken for GBS prevention are also not properly reported.

To date, only a single local study has been published in Malaysia. The prospective pilot study (n=56) was conducted almost two decades ago.[8] The researchers reported that the prevalence of GBS-positive mothers was 32.0%. However, perinatal outcomes of both mothers and neonates were not clearly reported.

Thus, the present study employed a comparative cross-sectional research design to elucidate the present prevalence of GBS colonisation among pregnant women and to evaluate maternal and neonatal outcomes by adopting universal GBS screening protocol. The findings will highlight the importance of GBS colonisation and its screening during pregnancy among pregnant women and medical practitioners. The results will also fill the current research gap and contribute to the local database. This will aid in clinical decision-making strategy, specifically on the construction and implementation of GBS screening programme protocol.

MATERIALS AND METHODS

This study was conducted at the Antenatal Clinic, Sultan Ahmad Shah Medical Centre (SASMEC)@IIUM, Kuantan, Pahang from October 2021 - May 2022. This study involved all pregnant women who were seen for follow-up at 35-38 weeks of gestation. Pregnant women with a previous baby affected by EOGBS, a known case of GBS bacteriuria in the current pregnancy, unable to understand Malay or English, and who has not consented to GBS screening tests were excluded.

The study sample size and power were calculated using OpenEpi, Version 3.01, an open-source calculator. The final estimated sample size for this study was based on the calculation of GBS colonisation rate. Using the single proportion formula and considering a maternal GBS colonisation rate of approximately 10-30%,[9] a precision level of 5-95% Confidence Interval, the calculated sample size was 197 participants. Upon considering a non -response rate of 20%, the estimated sample size was increased to 230 participants.

Data Collection

A convenient sampling method was employed in recruiting participants in this study. All pregnant women who fulfilled the inclusion and exclusion criteria were approached to participate in the study. Data was collected in three phases which were i) during clinic visits between 35-38 weeks of gestation, ii) immediately after delivery, and iii) at six weeks post-delivery.

Data on sociodemographic characteristics was collected using participant personal background form. Three samples were sent for GBS screening tests, including rectovaginal swab (RVS), high vaginal swab (HVS), and midstream urine (MSU). The samples were tested for GBS culture and sensitivity. For this study, the microbiology lab used Christie-Atkinson-Munch-Peterson (CAMP) test protocols to identify *Streptococcus agalactiae*, which is a Group B *Streptococcus* that produces a positive CAMP factor reaction. This method is gold standard test for antenatal *Streptococcus agalactiae* screening despite latest development in molecular testing for GBS, as sensitivity was improved with broth enrichment, and it allows for antibiotic susceptibility testing to be done.[10]

GBS screening results were reviewed through the hospital health electronic information system and documented in participants' electronic case notes. They were managed

accordingly based on their GBS status. GBS positive status is defined by the presence of at least one positive GBS culture in either RVS, HVS, or MSU culture. GBS is considered negative if all the tests were negative. Participants with positive cultures of GBS were covered with intrapartum antibiotic prophylaxis (IAP) as per Malaysian National Antimicrobial Guideline 2019.[10] Intravenous ampicillin 2g stat and 1g 4 hourly at the onset of labour or leaking was employed as the antibiotic of choice. In the case of participants allergic to penicillin, intravenous cefazolin, cefuroxime, vancomycin, or clindamycin was given as an alternative. In addition, participant with a high colony count positive GBS urine culture, taken as the value of ≥100 000 CFU/mL, was considered as GBS bacteriuria and recommended for appropriate antibiotics therapy at the time of diagnosis.[11] Participants with mixed colony were not considered and not treated for GBS bacteriuria. GBS bacteriuria was treated with oral amoxicillin 500 mg three times a day (TDS) for a week upon diagnosis. Repeated MSU culture and sensitivity was performed after one week post-antibiotics completion to ensure the clearance of infection.

After delivery, data related to perinatal outcomes was collected. PPROM is defined as ruptured membranes before 37+0 weeks of pregnancy but is not in established labour. Diagnosis was made by maternal history, followed by a sterile speculum examination demonstrating liquor. If, on speculum examination, no amniotic fluid is observed, tests such as Amniocator test of vaginal fluid or alkaline pH test strips were used for the amniotic fluid detection. Preterm labour is defined as, pregnancy presented with symptoms of labour before 37+0 weeks of gestation regardless of cervical changes. Whereas maternal pyrexia is defined as the presence of temperature of ≥38°C which developed after labour onset or within 24 hours post-delivery. Puerperal infection is defined as any new prescription of antibiotics for presumed or confirmed perineal wound-related infection, endometritis, uterine infection, urinary tract infection or other systemic infections.

Non-reassuring Apgar Score is defined as a score of 0-6. NICU or SCN admission means requirements for admission regardless of indication within Day 0-6 of life. Antibiotic administration to neonates is the requirement for antibiotics administration regardless of indication within Day 0-6 of life. For neonatal EOGBS, it is GBS disease confirmed by microbiological culture of blood, cerebrospinal fluid (CSF), or other sterile fluids taken on Day 0-6 of life.

All the data were extracted from the hospital electronic health information system. For participants that delivered in other hospitals, data were collected from the birth record in participants' antenatal and neonatal record books. Furthermore, after six weeks post-delivery, participants were contacted to inquire about any requirements of antibiotics treatment during the confinement period that signify puerperal infection.

Data Analysis

Data was analysed according to respective groups; either GBS-positive or GBS-negative, regardless of intrapartum antibiotic prophylaxis status. Participants' sociodemographic and clinical characteristics were analysed individually. All the data analyses were performed descriptively using SPSS Statistics 25 for Window. A chi-squared test was used for all categorical variables to assess if GBS colonisation differed by maternal and neonatal outcomes. Null hypotheses of no significant difference were rejected if $P<0.05$, signifying statistical significance.

Workflow Chart

Figure 1 illustrates the study workflow, showing a total of 230 pregnant women who agreed to participate in this study. However, only 215 were included for analysis after 15 were excluded due to various reasons as stated in the figure.

RESULT

Findings from this study showed that the prevalence of GBS-positive mothers was 58.6% (n = 126) based on either positive rectovaginal swab (RVS), high vaginal swab (HVS), or midstream urine (MSU). From the 126 positive cases, 79.4% were positive for RVS culture, while 60.3% and 38.9% were positive for HVS and MSU, respectively.

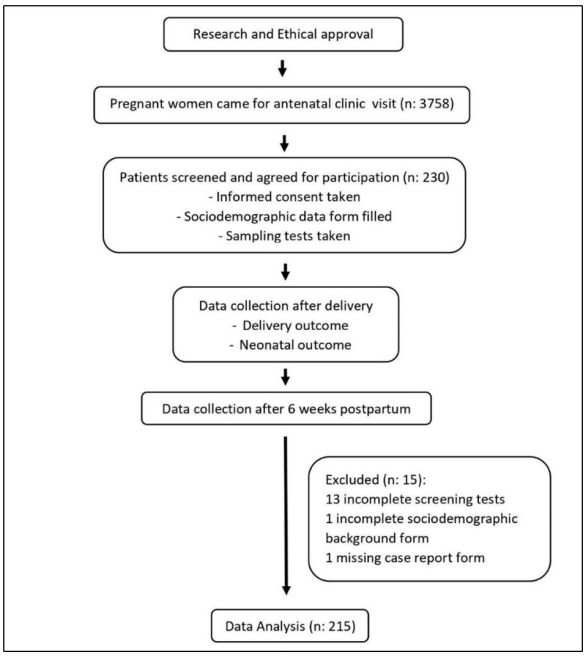

Figure 1: Workflow Chart

The sociodemographic characteristics of the participants is shown in Table 1. There was homogenous sociodemographic characteristics among the GBS-positive and GBS-negative mothers in the study population.

Table 1: Sociodemographic characteristics of the participants

	Overall, N (%)	GBS Status		P value
		GBS-positive, N (%)	GBS-negative, N (%)	
Age (years)	31.0 (4.4)*	30.6 (4.3)*	31.7 (4.6)*	0.071
Ethnic origin				0.000
Malay	183 (85.1)	118 (93.7)	65 (73.0)	
Chinese	26 (12.1)	8 (6.3)	18 (20.2)	
Indian	2 (0.9)	0 (0.0)	2 (2.2)	
Others	4 (1.9)	0 (0.0)	4 (4.5)	
Religion				0.002
Muslim	186 (86.5)	118 (93.7)	68 (76.4)	
Buddhist	26 (12.1)	8 (6.3)	18 (20.2)	
Christian	1 (0.5)	0 (0.0)	1 (1.1)	
Hindu	2 (0.9)	0 (0.0)	2 (2.2)	
Education level				0.088
Primary	1 (0.5)	1 (0.8)	0 (0.0)	
Secondary	50 (23.3)	23 (18.3)	27 (30.3)	
Tertiary	164 (76.3)	102 (81.0)	62 (69.7)	
Occupational status				0.772
Working	164 (76.3)	97 (77.0)	67 (75.3)	
Non-working	51 (23.7)	29 (23.0)	22 (24.7)	
Monthly household income				0.672
Low	122 (56.7)	74 (58.7)	48 (53.9)	
Middle	87 (40.5)	48 (38.1)	39 (43.8)	
High	6 (2.8)	4 (3.2)	2 (2.2)	

* mean (SD)

Table 2, shows the clinical characteristics of study participants. There was no significant association between GBS status and underlying clinical backgrounds, except for BMI (p=0.047). Using WHO BMI classification, mean BMI for GBS-positive mothers was 26.3 kg/m2 (overweight), while GBS-negative mothers was 24.8 kg/m2 (normal). Other medical illnesses included uncomplicated conditions such as asthma, COVID-19 positive, thyroid disease, and other haematological disorders, which were recorded in 10.2% of the participants.

Table 2: Clinical characteristics of participants

	Overall n (%)	GBS Status		P value
		GBS-positive n (%)	GBS-negative n (%)	
Parity				0.431
Primigravida	84 (39.1)	52 (41.3)	32 (36.0)	
Multipara	131 (60.9)	74 (58.7)	57 (64.0)	
Gestational Diabetes Mellitus				0.800
Yes	80 (37.2)	46 (36.5)	34 (38.2)	
No	135 (62.8)	80 (63.5)	55 (61.8)	
Hypertension				0.139
Yes	7 (3.3)	6 (4.8)	1 (1.1)	
No	208 (96.7)	120 (95.2)	88 (98.9)	
BMI* (kg/m2),	25.7 (5.5)^	26.3 (5.9)^	24.8 (4.8)^	0.047
Obesity				0.157
Yes	49 (22.8)	33 (26.2)	16 (18.0)	
No	166 (77.2)	93 (73.8)	73 (82.0)	
Anaemia				0.836
Yes	54 (25.1)	31 (24.6)	23 (25.8)	
No	161 (74.9)	95 (75.4)	66 (74.2)	
Other medical problems				0.387
Yes	22 (10.2)	11 (8.7)	11 (12.4)	
No	193 (89.8)	115 (91.3)	78 (87.6)	
Mode of Delivery				0.623
SVD**	153 (71.2)	89 (70.6)	64 (71.9)	
Vacuum	11 (5.1)	8 (6.3)	3 (3.4)	
Forceps	1 (0.5)	1 (0.8)	0 (0)	
LSCS***	50 (23.3)	28 (22.2)	22 (24.7)	

*BMI – body mass index, **SVD – spontaneous vertex delivery, ***LSCS – lower segment caesarean section. ^ mean (SD)

Maternal outcomes are described in Table 3. Though no maternal pyrexia was reported, 7.4% of mothers experienced puerperal infection over the course of first six weeks of postpartum, with no significant difference between the GBS status groups.

Table 3: Maternal outcomes

	Overall n (%)	GBS Status		P value
		GBS-positive n (%)	GBS-negative n (%)	
PPROM*				0.072
Yes	14 (6.5)	5 (4.0)	9 (10.1)	
No	201 (93.5)	121 (96.0)	80 (89.9)	
Preterm labour				0.392
Yes	16 (7.4)	11 (8.7)	5 (5.6)	
No	199 (92.6)	115 (91.3)	84 (94.4)	
Maternal pyrexia				N/A
Yes	0 (0.0)	0 (0.0)	0 (0.0)	
No	215 (100.0)	126 (100.0)	89 (100.0)	
Puerperal infection				0.392
Yes	16 (7.4)	11 (8.7)	5 (5.6)	
No	199 (92.6)	115 (91.3)	84 (94.4)	

**PPROM: Preterm pre-labour rupture of membrane*

Neonatal outcomes are described in Table 4. For neonatal outcomes, a similar pattern to maternal outcomes was observed. None of the neonatal outcomes depicted any significant difference in reference to maternal GBS colonisation. Two neonates were delivered with non-reassuring Apgar scores (0-6) and both were from the GBS-positive mothers. The neonates were delivered vaginally after a diagnosis of intrauterine death (IUD). Both cases presented with complaints of reduced foetal movement at term. Both mothers had no underlying complicated antenatal issues. Post-delivery assessment revealed no obvious congenital anomaly or syndrome. All cultures sent for IUD workup were negative for GBS.

Table 4: Neonatal outcomes

	Overall n (%)	Maternal GBS Status		P value
		GBS Positive n (%)	GBS Negative n (%)	
Gestational age				0.572
Preterm	10 (4.7)	5 (4.0)	5 (5.6)	
Term	205 (95.3)	121 (96.0)	84 (94.4)	
Apgar score				0.232
Non-reassuring	2 (0.9)	2 (1.6)	0 (0.0)	
Reassuring	213 (99.1)	124 (98.4)	89 (100.0)	
NICU/SCN* admission* **				0.064
Yes	79 (36.7)	53 (42.1)	26 (29.2)	
No	134 62.3)	71 (56.3)	63 (70.8)	
Antibiotic administration*				0.156
Yes	57 (26.5)	38 (30.2)	19 (21.3)	
No	156 (72.6)	86 (68.3)	70 (78.7)	
EOGBS**				N/A
Yes	0 (0.0)	0 (0.0)	0 (0.0)	
No	215 (100.0)	124 (100.0)	91 (100.0)	

*NICU/SCN – Neonatal Intensive Care Unit/Special Care Nursery
**EOGBS – Early neonatal GBS infection
***Two intrauterine death (0.9%) excluded for NICU/SCN admission and antibiotic administration analysis

DISCUSSION

Group B Streptococcus (GBS) Prevalence

In this study, 58.6% of pregnant mothers were tested positive for GBS colonisation, which is higher than the average worldwide estimation as stated in the initial hypothesis. CDC reported that worldwide colonisation rates vary, with estimated prevalence ranging from 10-30%.[2] The country with the highest GBS colonisation rate was Zimbabwe with 60.3% being infected at some point during pregnancy. Nevertheless, the colonisation rate decreased as the pregnancy progressed, falling to 21% at delivery, from 47% at 20 weeks to 24.2% at 26 weeks.[5] A study conducted in a university hospital in Kuala Lumpur reported 32% GBS-positive prevalence among patients visiting the antenatal clinic.[8]

The high prevalence of GBS-positive reported in this study, could be attributed to universal screening approach, which entailed three types of cultures for screening: HVS, RVS and MSU. In contrast, if only RVS culture was conducted, about 20% of mothers with GBS colonisation would not have received intrapartum antibiotics prophylaxis. This finding is consistent with a study conducted by Quinlan et al.[12] RVS culture was able to yield the highest GBS-positive results (80%) compared to HVS (60%) and MSU (39%).

Sociodemographic and Clinical Characteristics

The participants between both study groups were homogenous except for BMI, whereby GBS-positive mothers were likely to be overweight. A study in Spain concluded that maternal obesity poses a considerable and distinct risk for the occurrence of GBS colonisation at term.[13] Clinically, the present study population was mainly pregnant women at a lower risk with a low number of complicated medical comorbidities. However, the number of those with diabetes was higher compared to hypertension (37.2% vs 3.3%), which might be due to the higher prevalence of obesity (22.8%) and overweight (mean BMI) among the participants. The 25% anaemia rate among participants is slightly lower than previously reported rate among the general female population in Malaysian at 30%.[14]

Perinatal Outcomes

There was no significant difference in the perinatal outcomes between GBS-positive and GBS-negative mothers. There incidence of PPROM, preterm labour and puerperal infection reported in this study were within the global prevalence rate of 3-7%,[15] 5-10%,[16] and p 5-7%[17] respectively.

The pregnancy outcomes of GBS-positive mothers in this study, were associated with minimal complications, comparable to the general population following the implementation of GBS screening and intrapartum antibiotic prophylaxis. Moreover, this reflects the effectiveness of GBS screening and IAP practice as part of the preventive strategies against EOGBS.

Through no EOGBS was reported, 2 cases of IUD were documented in this study born to GBS-positive mothers, which should be considered as a significant burden. A study reported that 1% of stillbirths in developed nations and 4% in sub-Saharan Africa are caused by GBS cases.[18] Additionally, the study emphasised that GBS probably causes more deaths during antenatal period than after birth. However, till date, prelabour antibiotics therapy is not recommended in vaginal GBS colonization unless mother develop infection in the case of GBS bacteriuria.[19]

Study Strength, Limitations and Recommendations

This study is a comprehensive, comparative cross-sectional study where participants were followed up from pregnancy until delivery, while reporting the neonatal and puerperal outcomes. However, since this is not a multi-centre study, data obtained cannot be inferred to the Malaysian population. GBS prevalence and perinatal outcomes were not investigated or compared before employing the universal screening approach in the studied population; and, no adverse events that could be causally related to the IAP administration following GBS screening were studied.

For future studies, a larger sample size from multi-centres and multi-regional involvement should be conducted for optimal estimation of GBS colonisation rate and burden among pregnant mothers in Malaysia. Since GBS screening approach could be universal and risk-based, it is worth comparing how different approaches result in diverse outcomes among the Malaysian population. Thus, a randomised controlled trial could be considered in future studies. Further investigations are required to evaluate patients' response rate to GBS screening programme and their acceptance. A study on knowledge, attitude, and practice (KAP) can be conducted among patients, and practicing medical personnel. The findings obtained could be used to further guide the present health education strategies among Malaysian population and healthcare providers.

CONCLUSION

This study revealed a high prevalence of GBS (58.6%). However, the perinatal outcomes for GBS-positive mothers were favourable with widespread GBS screening and IAP administration, or at least comparable to those of GBS-negative mothers. Thus, GBS screening and IAP practice are effective to prevent maternal and neonatal complications related to GBS exposure. Based on these findings, the adoption of universal GBS screening approach is recommended as an effective method of GBS screening in the Malaysian population. The present data highlights the unmet need for routine GBS testing throughout pregnancy. This study also provides support for more research in this area, including studies on GBS screening strategy, KAP, cost analysis, and antibiotics resistance or adverse outcomes.

CONFLICT OF INTEREST

None

INSTITUTIONAL REVIEW BOARD (ETHICS COMMITTEE)

The ethical approval was obtained from the IIUM Research Ethics Committee (IREC) on 20th September 2021 (Approval number: IREC 2021-251).

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