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Group B Streptococcus Carriage in Pregnancy: Burden of Early-onset Neonatal Disease and Estimation of the Cost of Universal Antenatal Screening in a Hospital of the Eastern Region of Saudi Arabia

Gebelikte Grup B Streptokok Taşıyıcılığı: Suudi Arabistan'ın Doğu Bölgesindeki Bir Hastanede Erken Başlangıçlı Neonatal Hastalığın Yükü ve Evrensel Doğum Öncesi Taramanın Maliyetinin Tahmini

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Abstract

Introduction: Group B streptococcus (GBS) is recognized as a significant cause of neonatal infections worldwide. The study investigated the burden of early-onset neonatal disease and assessed the cost of routine GBS screening in a hospital of the eastern region of Saudi Arabia.
Materials and Methods: Pregnancy-related information and laboratory-related data for pregnant women for the period of 2016-2017 were used to determine the colonization rate of GBS. The efficiency of intrapartum antibiotic prophylaxis (IAP) was examined among pregnant women carrying GBS and delivered at the hospital. The cost of GBS routine screening was estimated based on the cost of rectovaginal swab enrichment in BBL™ LIM broth and confirmation by polymerase chain reaction. The burden of early-onset disease and rates of resistance to antibiotics among vaginal and invasive neonatal isolates were investigated for seven years.
Results: Screening of 2,476 samples from 1,162 pregnant women in two years showed a GBS colonization rate of 23% (270/1162). Of the 270 GBS-positive women, only 98 (37%) delivered at the hospital, of whom 42% received IAP. Cesarean delivery was associated with significantly higher rates of IAP administration (odds ratio 5.2; p value 0.001). The annual incidence of early-onset disease increased from a baseline level of 0.5 in 2012 to 3.9 per 1,000 births in 2018. These included 23 cases of invasive infections with three fatal cases caused by meningitis or sepsis (3/23, 13%). Group B streptococcus isolates remained uniformly sensitive to penicillin and vancomycin but exhibited resistance to clindamycin in 35.2%. The annual estimated costs of routine screening would be $110,880 ($41 per delivery) and $161,280 ($60 per delivery) for the BD MAX™ system and GeneXpert® System, respectively.
Conclusion: While the incidence of early-onset GBS disease was increasing, improved compliance with the IAP is needed to inform the cost-effectiveness of routine GBS screening.
Keywords: *S. agalactiae*, neonatal sepsis, clindamycin resistance, early onset

Öz

Giriş: Grup B streptokok (GBS), dünya çapında neonatal enfeksiyonların önemli bir nedeni olarak kabul edilmektedir. Bu çalışmada, Suudi Arabistan'ın doğu bölgesindeki bir hastanede erken başlangıçlı yenidoğan hastalığının yükü araştırıldı ve rutin GBS taramasının maliyeti değerlendirildi.

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Öz

Gereç ve Yöntem: Grup B streptokok kolonizasyon oranının belirlenmesinde 2016-2017 dönemine ait gebelik bilgileri ve gebelere ait laboratuvar verileri kullanıldı. Grup B streptokok taşıyan ve hastanede doğum yapan gebelerde intrapartum antibiyotik profilaksisinin (IAP) etkinliği araştırıldı. Grup B streptokok rutin taramasının maliyeti, BBLTM LIM sıvı besiyerinde rektovajinal sürüntü zenginleştirme ve polimeraz zincir reaksiyonu ile doğrulama maliyeti temel alınarak tahmin edilmiştir. Vajinal ve invaziv neonatal izolatlar arasında erken başlangıçlı hastalık yükü ve antibiyotiklere direnç oranları 7 yıllık bir süre boyunca araştırılmıştır.
Bulgular: Bin yüz altmış iki hamile kadından alınan 2.476 numunenin iki yıllık bir süre boyunca taranması %23 (270/1162) GBS kolonizasyon oranını gösterdi. İki yüz yetmiş GBS pozitif kadından yalnızca 98'i (%37) hastanede doğum yaptı ve bunların %42'si IAP aldı. Sezaryenle doğum, anlamlı derecede daha yüksek IAP uygulama oranıyla ilişkilendirildi (olasılık oranı 5,2; p değeri 0,001). Erken başlangıçlı hastalığın yıllık insidansı 2012'de 1000 doğumda 0,5 olan başlangıç düzeyinden 2018'de 1.000 doğumda 3,9'a yükseldi. Bunlar arasında menenjit veya sepsis nedeniyle üç ölümcül olguyla birlikte 23 invazif enfeksiyon olgusu yer alıyordu (3/23, %13). Grup B streptokok izolatları penisilin ve vankomisine karşı eşit derecede duyarlı idi ancak klindamisine karşı %35,2 oranında direnç gösterdi. Rutin taramanın yıllık tahmini maliyeti, BD MAX™ sistemi ve GeneXpert® Sistemi için sırasıyla 110.880$ (doğum başına 41$) ve 161.280$ (doğum başına 60$) olarak belirlenmiştir.
Sonuç: Erken başlangıçlı GBS hastalığının görülme sıklığının arttığı gösterilirken, rutin GBS taramasının maliyet etkinliği hakkında bilgi vermek için IAP ile daha iyi uyum sağlanması gerekmektedir.
Anahtar Kelimeler: *S. agalactiae*, yenidoğan sepsis, klindamisin direnci, erken başlangıçlı

Introduction

Invasive Group B streptococcal (GBS) disease emerged in the 1970s worldwide as a leading cause of infections in the first week of life, i.e., early onset[1]. The incidence of invasive neonatal GBS infections range from 0.5 to 3.0 per 1,000 live births, with 4-10% mortality associated with early-onset infections[2,3]. In early-onset disease, GBS can be acquired during labor or in utero by transmission from maternal vaginal or anorectal colonized mucosa. In the 1980s, clinical trials showed that the administration of antibiotic prophylaxis during labor and delivery to mothers who had GBS colonization may minimize the incidence of early-onset GBS disease[4]. During the 1990s, intrapartum antibiotic prophylaxis (IAP) administered to candidates according to a screening- or a risk-based strategy led to a 65% reduction in the incidence of early-onset GBS disease, from 1.7 cases per 1,000 live births in 1993 to 0.6 cases per 1,000 live births in 1998[5-7]. In 2002, national guidelines were updated in the USA, with the recommendation of universal culture-based screening of all pregnant women[8,9]; however, this strategy was not adopted in the UK where the risk-based IAP administration strategy continues[10].

A large geographical variation exists in the rates of asymptomatic rectovaginal colonization with GBS, occurring in approximately 10-30% of pregnant women in different regions globally[3]. Despite the availability of excellent GBS data among developed countries, there is a paucity of information on rectovaginal colonization and associated maternal and neonatal complications of GBS among many resource-limited countries. Indeed, evidence on maternal colonization prevalence remains sparse in the Middle East and Gulf States[3]. The introduction of the IAP in the developing world could reduce the number of infants who die from neonatal sepsis annually. However, to determine the likely effect and provide recommendations for the optimal strategy of antibiotic administration, the prevalence of GBS colonization and pattern of antibiotic susceptibility of clinical isolates in the target population must be determined.

In Saudi Arabia, pregnant women are not routinely screened for rectovaginal GBS colonization. As a result, data on the prevalence, antimicrobial susceptibility pattern, serotypes, and risk factors of rectovaginal GBS colonization are limited. Few local and regional GBS studies conducted in Saudi Arabia have reported maternal GBS colonization rates ranging between 9.2% and 31.6%[11-16]. However, no study has been conducted in the eastern region of Saudi Arabia (i.e., Al-Qatif governate), and none of the studies have evaluated the cost of routine screening. Thus, this study aimed to determine the carriage rate of GBS among pregnant women and the burden of invasive neonatal GBS disease and estimate the cost of GBS routine screening by polymerase chain reaction (PCR). Another aim was to evaluate IAP utilization for GBS-positive women and antimicrobial susceptibility patterns of GBS isolates.

Materials and Methods

Study Setting

The study was conducted at Qatif Central Hospital, a district general hospital providing healthcare services in Al-Qatif governate that is located in the eastern region of Saudi Arabia. The hospital serves a population of more than half a million and has two maternities providing admission services to 200-250 pregnant women for delivery each month. The study population included pregnant women between the gestational ages of 12 and 40 weeks receiving antenatal care between January 2016 and December 2017. Patient information (2016-2017) and microbiology testing data were compiled from the

Hospital Information System (MedicaPlus™, Riyadh, Saudi Arabia). Collected information included the mode of delivery, gestational age, and culture results of newborn babies. During the study period, no systematic screening was conducted for the GBS carriage in pregnancy, and IAP administration has not been established in the hospital. Pregnant women with complications such as endometritis and chorioamnionitis were excluded, and antimicrobial agents prescribed for complications were not considered prophylaxis. Women who had two deliveries during the study period were counted twice. Pregnant women who were GBS carriers and delivered at the hospital were further analyzed for IAP. In addition, the incidence of early-onset invasive GBS disease in seven years (2012-2018) was determined. The burden of early-onset GBS disease was expressed as numbers per 1,000 live births.

Definitions

GBS carriage was defined as any documented prenatal vaginal culture result that was performed before delivery. Delivery earlier than 37 weeks of gestation was considered preterm delivery. Intrapartum was defined as the period between labor onset or rupture of the membranes and delivery. In cesarean deliveries, intrapartum was defined as the period between admission for labor or delivery and cord clamping. Early-onset invasive GBS disease was defined by GBS isolation from a normally sterile site (blood and/or cerebrospinal fluid) in a live-born infant aged <7 days.

GBS Isolation

In the laboratory, vaginal swabs received for culture were inoculated onto 5% defibrinated sheep blood agar plates [Saudi Prepared Media Laboratory (SPML), Saudi Arabia], streaked, and incubated for 18-24 h at 36°C supplemented with 5% CO_2. Most of these swabs were received as part of the examination for vaginitis and were inoculated onto Sabaroud Dextrose agar for *Candida* spp., and wet mounts were prepared for the examination for the presence of *Trichomonas vaginalis*. Blood agar plates with no evidence of GBS colonies were reincubated for another 24 h in the same atmosphere. Suspected colonies were identified using conventional microbiological methods, including Gram stain, catalase and CAMP tests, and latex agglutination grouping.

Antimicrobial Susceptibility Testing

Rates of susceptibilities to clinically relevant antibiotics among all isolates recovered from vaginal cultures and invasive sites of neonates aged <7 days in seven years (2012-2018) were investigated using the WHONET, a free software developed by the WHO Collaborating Centre for Surveillance of Antimicrobial Resistance[17]. Susceptibility testing was performed using the disc diffusion method following the recommendation of the Clinical and Laboratory Standards Institute (CLSI)[18]. Group B streptococcus colonies were tested against penicillin G, ampicillin, cefotaxime, vancomycin, erythromycin, and clindamycin. Briefly, the turbidity of the emulsified colonies was adjusted to 0.5 McFarland and inoculated on Muller-Hinton Agar enriched with 5% sheep blood. Then, discs were placed on the surface of the inoculated plate equidistant from each other and incubated at 36 °C with a 5% CO_2 atmosphere for 18-24 h. The inhibition zones were interpreted as set by CLSI[18]. Inducible resistance to clindamycin was checked by the double-disc diffusion test (D-test) for isolates appearing susceptible to clindamycin and resistant to erythromycin. D-tests were performed by placing erythromycin (15 µg) and clindamycin (2 µg) discs 12 mm apart edge-to-edge on Mueller-Hinton agar supplemented with 5% sheep blood agar (SPML) that had been inoculated with a 0.5 McFarland suspension of the organism[19]. The plates were incubated for 24 h at 36 °C in 5% CO_2. Blunting of the clindamycin inhibition zone proximal to the erythromycin disc was considered clindamycin resistant because of inducible macrolide-lincosamide-streptogramin$_B$ (iMLS$_B$) methylation.

Estimation of the Universal Screening Cost

We attempted to estimate the annual cost of routine screening using two commercial PCR systems. By taking the average annual delivery, the quotation for the BBL™ LIM broth [Becton Dickinson (BD), Saudi Arabia], and the cost of the PCR test for BD MAX™ and GeneXpert® systems, the estimated cost of routine screening was calculated. In addition, using data collected from women attending antenatal care with a request for vaginal culture during the study period, the estimated cost of screening for two years was calculated.

Results

Maternal Colonization and Demographic Characteristics

The screening of 2476 samples collected between January 2016 and December 2017 from 1,162 women at 12-40 weeks of gestation showed 23% (270/1162) GBS positivity. Of the 270 GBS-positive pregnant women, 98 (37%) had delivery in the hospital and were further investigated. Group B streptococcus-positive participants were between 17 and 46 years old, with a median age of 34 years. Moreover, 16% (n=43) were ≤25 years old compared with 44% (n=119) and 40% (n=108) aged 26-35 and >35 years, respectively. Among GBS-positive pregnant women who had hospital delivery, 28% (27/98) gave birth by cesarean section, and 24% (23/98) were preterm (Table 1).

Antibiotic Prophylaxis Administration

IAP was given to 42% (41/98) of pregnant women with GBS-positive cultures, of whom 46% (19/41) had cesarean deliveries (Table 1). Mothers who gave birth by cesarean section were

Table 1. Demographic and obstetrical characteristics of the GBS-positive group with hospital delivery

Participant characteristics	Total (n=98) (%)	Prophylaxis		
		Ampicillin	Cefazolin	Not given
Age (years)				
≤25	21 (21%)	5 (24%)	3 (14%)	13 (62%)
26-35	45 (46%)	9 (20%)	11 (24%)	25 (56%)
≥36	32 (33%)	6 (19%)	7 (22%)	19 (59%)
Gestational age				
Full term	75 (77%)	15 (20%)	14 (19%)	46 (61%)
Preterm	23 (24%)	4 (17%)	8 (35%)	11 (48%)
Delivery				
Vaginal	71 (72%)	15 (21%)	7 (10%)	49 (69%)
Cesarean section	27 (28%)	4 (15%)	15 (56%)	8 (30%)
Total		19 (19%)	22 (22%)	57 (58%)

GBS: Group B streptococcus

significantly more likely to receive antibiotic prophylaxis than mothers with normal deliveries (odds ratio 5.2; p value 0.001; 95% confidence interval: 2.01-13.88). Although statistically not significant, the rate of IAP administration was higher among GBS-positive women who delivered preterm compared with full-term delivery (52% vs. 39%, respectively). Ampicillin was used as antibiotic prophylaxis in 46% (19/41) of the cases, whereas cefazolin was used in 54% (22/41). This study had no record of the administration of clindamycin or vancomycin as prophylaxis. Ampicillin was administered as 1 g every 4 h until delivery, with a 2 g loading dose in only 63.2% (12/19) of cases. Cefazolin was uniformly prescribed as the initial dose 2 g, followed by 1 g every 8 h until delivery. In 2016 and 2017, none of the babies born to mothers with GBS-positive cultures developed early-onset -invasive GBS infection.

Early-onset Neonatal Disease

The annual prevalence of early-onset GBS disease increased from a baseline level at 0.5 in 2012 to 3.9 per 1,000 births in 2018 (Figure 1). In seven years, 23 cases were identified with a 13% 30-day mortality; three cases presented with sepsis and meningitis (Figure 2). Among the infected infants, 20 (87%) were born to untested mothers, one had a mother tested positive (4.3%), and one was of a mother with negative culture results in the gestational period; one baby was born of a mother with documented GBS urinary tract infection.

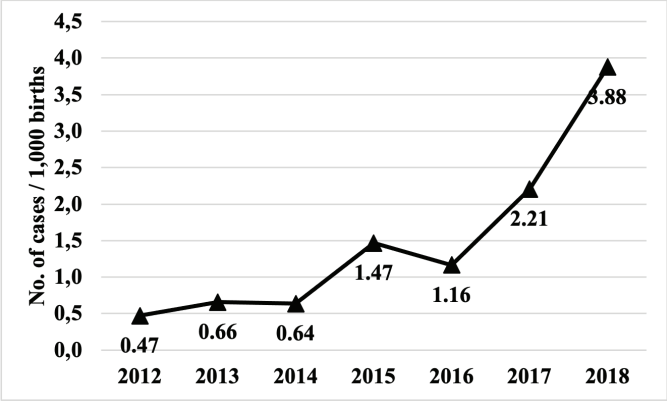

Figure 1. Incidence of early-onset Group B streptococcus disease

Antimicrobial Susceptibility Results

In the antimicrobial susceptibility surveillance from 709 GBS isolates showed no resistance to penicillin G, ampicillin, cefotaxime, or vancomycin. Non-susceptibility to erythromycin and clindamycin among all vaginal and early-onset invasive GBS isolates was observed in 42% and 35%, respectively. Among the erythromycin-resistant isolates, 18% showed inducible MLS_B resistance to clindamycin detected by the double-disc diffusion method. Data demonstrated a significant increase in clindamycin resistance rates from 10.6% in 2012 to 50.4% in 2018 (Figure 3).

Estimation of the Cost of Routine Screening

Based on the average number of 2,700 deliveries annually, the annual estimated cost of universal GBS screening from

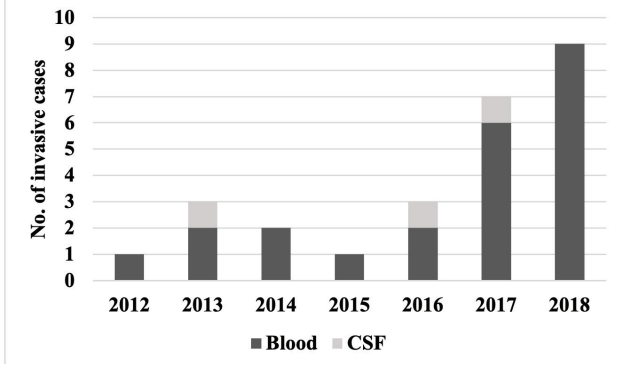

Figure 2. Sepsis and meningitis cases of early-onset Group B streptococcus disease

CSF: Cerebrospinal fluid

vaginal/rectal swabs collected at 35-37 weeks of gestation and enriched in BBL™ LIM broth would be $110,880 ($41 per delivery) and $161,280 ($60 per delivery) for BD MAX™ and GeneXpert® systems, respectively (Figure 4). The estimated cost of screening of all pregnant women who attended the antenatal care with vaginal culture for the study period was $47,719 and $69,410 for the BD MAX™ and GeneXpert® systems, respectively. Given that approximately 37% of pregnant women receiving antenatal care services had hospital delivery, the estimated expense loss from unnecessary screening for the study period (i.e., 63%) would be $30,062 and $43,728 for BD MAX™ and GeneXpert® systems, respectively.

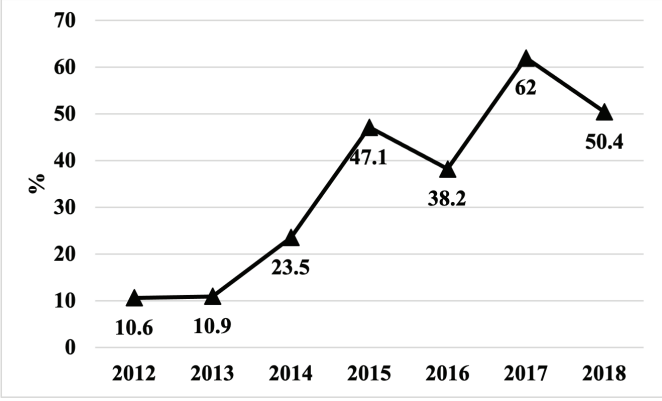

Figure 3. Clindamycin resistance in Group B streptococcus

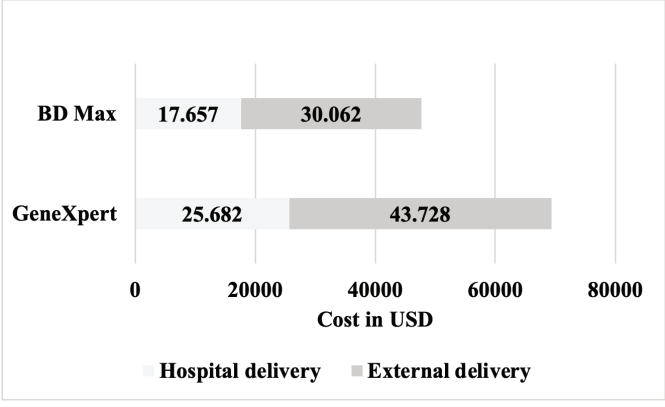

Figure 4. Estimated annual cost of Group B streptococcus screening by polymerase chain reaction

Discussion

This study describes the burden of early-onset GBS disease and estimates the cost of routine GBS screening in pregnancy. Our investigation revealed a 7.3-time increase in the overall incidence of early-onset disease in the absence of systematic screening or widespread IAP, increasing from 0.47 in 2012 to 3.9 per 1,000 live births in 2018. The case fatality rate for early-onset disease is approximately 4-10%[2,3]. This is similar to our finding of a 13% mortality rate among invasive GBS disease. The most common diagnosis with early-onset disease is bacteremia (89%); meningitis, but not bacteremia, is diagnosed in 10%, and both bacteremia and meningitis in 1%[3]. However, all early-onset GBS disease cases from this study presented with bacteremia, of which 16.7% presented with meningitis and bacteremia.

A recent review including a total of 299,924 pregnant women from 85 countries showed that the adjusted estimate for maternal GBS colonization worldwide was 18% with regional variation from 11% (Eastern Asia) to 35% (Caribbean)[20]. Although few studies have revealed that the maternal colonization rate among pregnant women from different parts of Saudi Arabia ranges from 9.2% to 31.6%[11-16], no study has been reported from the Al-Qatif area. The colonization rate of 23% obtained in this study is within the range reported previously both from developed and developing countries and is consistent with findings in countries such Palestine (21%)[21] and subregions of Africa such as North Africa (22.9%)[20]. Our result is also similar with those obtained by a single-center study conducted in Riyadh, Saudi Arabia[15]. However, slightly lower rates of 7-20% were reported from Iran[22], United Arab Emirates[23], Kuwait[24], Tunisia[25], Alkhobar, and Saudi Arabia[11,12]. By contrast, higher GBS colonization rates (>23-31.6%) were reported from Egypt[25], Iran[26], and different parts of Saudi Arabia[13,14]. The variations in the prevalence of GBS colonization, even among people who share geographical boundaries and have similar socioeconomic conditions, may be explained by the gestational age at culturing, differences in culture sites and culture techniques, change in prevalence with time, or real differences of the prevalence in different populations or ethnic groups[27,28]. For instance, Khalil et al.[29] found a 55% positive predictive value for antepartum rectovaginal swab cultures compared with 78% for bed-site intrapartum PCR.

The documented colonization rate for GBS is far higher than the attack rate in terms of neonatal infections. In the absence of any intervention, approximately 1-2% of infants born to mothers with colonization develop early-onset GBS infections[3]. Because of the severity of neonatal infection in early-onset GBS, major efforts have been directed toward the use of IAP in pregnant women whose genital tracts are colonized with GBS. Various strategies for the use of IAP are employed globally with risk-based IAP administration in the UK[10] and a universal culture-based screening program in the USA[3], probably arising from the difference in incidence rates, interpretation of available evidence, and cost-effectiveness analysis of screening programs and antibiotic prophylaxis. However, in Saudi Arabia, no systematic screening for GBS colonization in pregnant women has been implemented, and the provision for widespread IAP was not developed. Active population-based surveillance in

the USA showed that universal screening resulted in a 38% decrease in the incidence of early-onset GBS disease, from 0.37 cases per 1,000 live births in 2006-2015 to 0.23 cases per 1,000 live births[30]. This supports the need for the development and implementation of a strategy to utilize IAP based on universal screening and preferably on the existing risk factors for all pregnant women. However, only 42% of the pregnant women with documented GBS-positive culture before the hospital delivery received IAP, suggesting that the implementation of a universal screening approach to prevention poses challenges. Mothers who delivered preterm were more likely to receive IAP than mothers who delivered at term, a finding that was different from the results based on less use of prophylaxis among mothers who delivered preterm reported by Van Dyke et al.[31]. Although cefazolin is recommended in those who are allergic to penicillin but at low risk for anaphylaxis[3], cefazolin was used in 53.6% of women without any evidence of penicillin allergy, unlike the use of ampicillin in 76.7% of cases previously reported[31].

The antibiotic susceptibility patterns of GBS obtained in this study are in agreement with the results of previous worldwide studies[3,32-34] and confirm its predictable empiric susceptibility to penicillin and ampicillin, although bacteria with increasing minimum inhibitory concentration to penicillin and ampicillin have been reported[3,34]. Vancomycin is recommended in mothers with GBS colonization and high risks of anaphylaxis to penicillin and if the isolate is resistant to clindamycin[3]. Resistance of GBS to clindamycin has already been reported, ranging from 7% to 55.7%[32,35,36]. In this study, resistance to clindamycin and erythromycin was observed in 35% and 42%, respectively, indicating the need for isolating GBS and performing susceptibility testing before clindamycin administration. Similar resistance rates have been reported in the USA[37,38], whereas other studies have reported higher resistance rates in Palestine[21] and China[32]. However, lower resistance rates have been reported in Makkah and Riyadh in which GBS strains exhibited 15.7% and 10% resistance to erythromycin and 5.1% and 6% to clindamycin, respectively[15,16]. The differences in antibiotics use, prophylaxis practice, widespread and indiscriminate use of these antibiotics in various clinical cases, variation in susceptibility test methods, and/or disparities in serotype distribution may result to regional differences in the resistance rates of GBS to different antibiotics.

Since vaginal and particularly rectal flora contains numerous microorganisms, the CDC recommends the use of selective culture medium to maximize GBS isolation and avoid the overgrowth of other organisms[3], although a recent study found that enrichment broth resulted in a slightly improved sensitivity of culture results[39]. LIM broth (Todd-Hewitt broth supplemented with selective antibiotics), followed by PCR, offers several advantages such as decreased workload because no subculture is needed and decreased time to detection, i. e., at least 24 h faster than the standard method. However, subculture on sheep's blood agar is required if antibiotic susceptibility results are needed. In this study, nearly two-thirds of the estimated cost would be considered waste because only 37% of women receiving antenatal care had hospital delivery. In addition, IAP was given to only 42% of pregnant women with GBS colonization and hospital delivery, suggesting a need for improving compliance with IAP by the development of a comprehensive program. This study also estimated an annual cost of more than $100,000 should a universal screening strategy is introduced in our hospital. To conduct a universal screening program, an adequate number of staff and facilities (space and storage area) and the use of enrichment broth and selective agar or PCR are needed. Major organizational changes and new funding are required to ensure an equitable and quality-assured service.

Study Limitations

As its limitations, serotyping of GBS isolates was not performed. In addition, the use of IAP for GBS-negative pregnant ladies based on risk factors was not determined.

Conclusion

To the best of our knowledge, this is the first study conducted in Al-Qatif area to determine GBS colonization among pregnant women and one of the very few studies reporting the cost estimation of universal screening. Although a high GBS colonization rate was found among pregnant women seeking antenatal care services and an increasing incidence of early-onset GBS disease, the cost-effectiveness of the universal antenatal screening cannot be endorsed without improving compliance with IAP and performing an economic analysis study. Until effective vaccines against GBS are available for clinical use, the development and implementation of rapid and sensitive techniques for GBS screening at presentation may help prevent additional cases of invasive GBS disease. More studies are needed to ensure the effectiveness of IAP and whether there are any long-term adverse effects on mothers or babies. The development of vaccines against GBS continues to hold the most promising strategy for further prevention of early-onset GBS disease.

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Ethics

Ethics Committee Approval: The study was approved by the Local Institutional Review Board at Qatif Central Hospital (protocol no: QCH-SREC0118, date: 12.11.2023).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Design: A.M.A-H., Data Collection or Processing: A.M.A-H., M.A., R.G., M.A-I., Analysis or Interpretation: A.M.A-H., M.M.A., M.A., R.G., M.A-I., Literature Search: A.M.A-H., Writing: A.M.A-H.

Conflict of Interest: No conflict of interest was declared by the authors.

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