The Journal of Maternal-Fetal & Neonatal Medicine

ISSN: 1476-7058 (Print) 1476-4954 (Online) Journal homepage: http://www.tandfonline.com/loi/ijmf20

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To cite this article: Teresa W. L. Ma, Viola Chan, C. H. So, Annie S. Y. Hui, C. N. Lee, Amelia P. W. Hui, P. L. So, C. W. Kong, Barbara Fung & K. Y. Leung (2017): Prevention of early onset group B streptococcal disease by universal antenatal culture-based screening in all public hospitals in Hong Kong, The Journal of Maternal-Fetal & Neonatal Medicine, DOI: 10.1080/14767058.2017.1300649

To link to this article: http://dx.doi.org/10.1080/14767058.2017.1300649

Published online: 21 Mar 2017.

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE, 2017
http://dx.doi.org/10.1080/14767058.2017.1300649

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ORIGINAL ARTICLE

Prevention of early onset group B streptococcal disease by universal antenatal culture-based screening in all public hospitals in Hong Kong

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ABSTRACT

Objectives: To determine the prevalence of maternal colonization with group B streptococcus (GBS), and early onset GBS disease (EOGBSD) after implementation of universal screening.

Methods: This was a three-year retrospective cohort study on universal antenatal rectovaginal culture-based screening and intrapartum antimicrobial prophylaxis (IAP) to colonized women in the public sector in Hong Kong. Routinely collected data including maternal colonization and EOGBSD were retrieved.

Results: Of 113,989 GBS screening performed, 21.8% were positive. The colonization rate was higher in the public hospitals (higher risk) than in the Maternal and Child Health Centers (lower risk) (23.7% vs 18.1%, $p < .001$), while their false negative rates were not greater than expected. Majority of eligible women opted for screening, and colonized women received IAP. There were 29 cases of EOGBSD with clinical signs and a positive blood or cerebrospinal fluid culture. Compared to clinical risk-based screening, EOGBSD incidence decreased after universal screening (1 vs 0.24 per 1000 births, $p < .001$). Although EOGBSD occurred at a higher rate in preterm than term infants, 86.7% occurred in the latter, and were associated with a false negative screening result (41.3%), lack of screening (20.7%) or unavailability of a colonization result at labour (13.8%).

Conclusions: Maternal GBS colonization rate was higher than previously reported, and varied with different risk populations. EOGBSD reduced after universal screening.

ARTICLE HISTORY
Received 14 December 2016
Revised 4 February 2017
Accepted 24 February 2017

KEYWORDS
Group B streptococcus; intrapartum antibiotic prophylaxis; incidence; prevention; risk factors; sepsis

Introduction

Group B streptococcus (GBS) is an important cause of severe early onset neonatal infection with mortality and illness including meningitis [1,2]. Timely intrapartum antibiotics prophylaxis (IAP) given to high risk women can effectively reduce the GBS colonization rate of newborns and hence the incidence of early onset GBS disease (EOGBSD) [3]. How to identify these high risk women varies among different countries and places probably because of the differences in their background incidences of EOGBSD, proportion of pregnant women with risk factors, and clinical practice [4–6]. While universal culture-based screening has been recommended by the Centers for Disease Control and Prevention [1] and risk-based screening by the Royal College of Obstetricians and Gynaecologists [7].

The use of universal culture-based screening and IAP was associated with a reduction in the incidence of EOGBSD in the U.S. by approximately 80% since the early 1990s [8,9]. However, there are remaining problems including inadequate GBS screening; unavailability of a colonization result at labour, preterm delivery, incorrect IAP, and false negative GBS screening results [5,10–12].

Prior to 2009, all the public hospitals in Hong Kong used the clinical risk-based screening strategy to prevent EOGBSD, and its incidence was around 1.0 per 1000 births [13]. From 1 April 2009 to 31 March 2010, a pilot study on universal culture-based screening was

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conducted in one public hospital, and the results showed its feasibility and cost effectiveness [13]. Since 1 January 2012, all eight public hospitals with obstetric services in Hong Kong in collaboration with 27 Maternal and Child Health Centers have implemented the universal culture-based screening. The objectives of our present study are to determine the prevalence of maternal colonization with GBS, and EOGBSD after implementation of the universal culture-based screening in all public hospitals in Hong Kong.

Materials and methods

This was a retrospective cohort study reviewing the performance of the universal culture-based screening program in the prevention of EOGBSD in the public health care system of Hong Kong. All eight public hospitals with obstetrics services under the Hospital Authority and 27 Maternal and Child Health Centers under the Department of Health participated in this program. This study has been approved by the local ethics committee or institutional review board at each participating site, and patients' consent was not required because this study was a retrospective one.

Routine culture-based screening program

After the successful pilot project in 2009–10 [13], a standard protocol, counselling information and logistic workflow (Figure 1) were developed and agreed by all eight public hospitals with obstetric services and 27 Maternal and Child Health Centers. From 1 January 2012 to 31 December 2014, all pregnant women seeking antenatal care in our public health care system were offered routine GBS screening by taking low vaginal and rectal swabs by a trained midwife/nurse at 35–37 weeks' gestation according to a standard protocol in the antenatal clinics after explanation and checking the risk factors (Figure 1). As low-risk pregnant women were shared care between a public hospital and a Maternal and Child Health Center, swabs were taken at an antenatal clinic in either place when a woman was first seen within the swab taking period, and documentation of GBS screening was made. If swabs were not taken at 35–37 weeks' gestation because a woman did not attend as scheduled or other reasons, swabs would be taken when she returned to an antenatal clinic or was admitted. If swabs had been taken in the private sector at 35–37 weeks' gestation, swabs would not be repeated by us in the public setting.

Two swabs, one from the lower vagina (vaginal introitus) and the other from the rectum (swab through the anal sphincter), were taken and placed into a single nonnutritive transport medium. Although one combined swab can be taken from both sites [14], we preferred two different swabs, with a higher cost, for the hygiene of the women. If processing was delayed, the swabs would be placed in a refrigerator for storage. The swab specimens taken in the Hospital Authority and Maternal and Child Health Centers were sent to the microbiology laboratory of the Hospital Authority and Department of Health, respectively. GBS was tested using enrichment broth followed by subculture according to the guidelines from the Centers for Disease Control and Prevention [14]. Antibiotics susceptibility testing was also performed according to the guidelines from Clinical and Laboratory Standards Institute.

The Hospital Authority report on GBS could be retrieved electronically from the antenatal record system while the Department of Health report on GBS, in paper, would be faxed to the concerned Maternal and Child Health Center and the shared care hospital. If GBS screening was positive, IAP would be given during labour in the Hospital Authority hospitals according to the CDC guidelines 2010 [1] while antibiotics would not be given to an asymptomatic woman during antepartum. All infants born to mothers with GBS colonization were managed by a paediatrician.

Outcomes and data collection

The main outcome measures including maternal GBS colonization rate, EOGBSD (isolation of GBS from blood or cerebrospinal fluid, a normally sterile site in live-born infant less than seven days of age) and mortality were retrieved from the clinical and laboratory database of the Hospital Authority and statistical returns of Maternal and Child Health Centers. We checked the data accuracy by comparing the data generated from the database with manual collection. Maternal and infant clinical records were reviewed for confirmed cases of EOGBSD. The latter was diagnosed by the presence of clinical signs and isolation of GBS from blood or cerebrospinal fluid.

The screening rate in the Maternal and Child Health Centers and IAP rate in the Hospital Authority were assessed in the initial study period.

Statistical analysis

Data were presented using descriptive statistics. Distributions of categorical variables were compared using Pearson's chi-square test, and two-tailed p values of less than .05 were considered statistical significance.

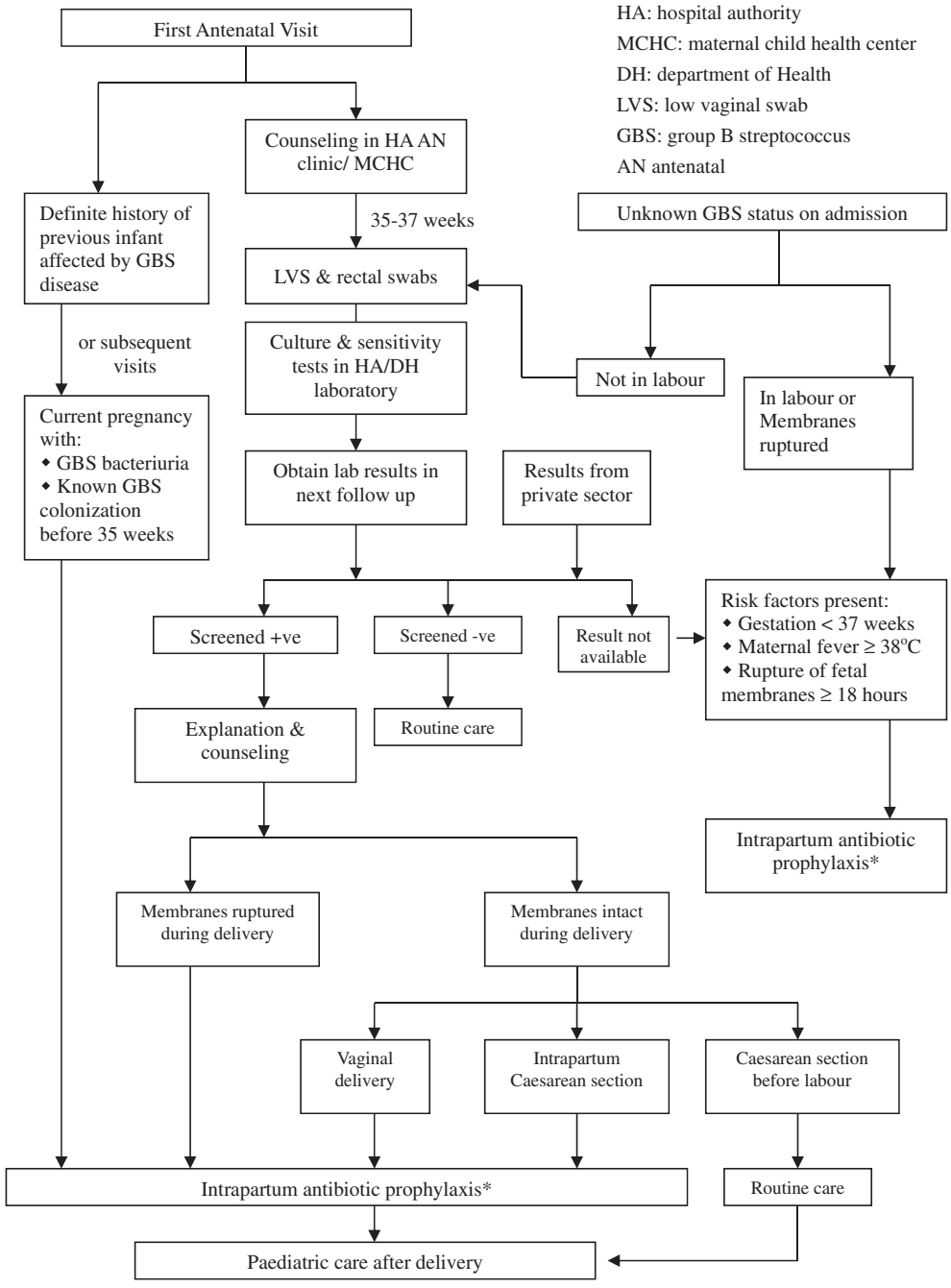

Figure 1. Obstetric workflow of universal swab-based screening and intrapartum antibiotics prophylaxis. HA: hospital authority; MCHC: maternal child health center; DH: Department of Health; LVS: low vaginal swab; GBS: group B streptococcus; AN: antenatal.

Statistical analyses were performed using SPSS 20.0 for Windows (SPSS Inc., Chicago, IL). We determined the anticipated numbers of false negative and failed IAP using the following assumptions and equations [11,12].

Assuming that the universal culture-based screening was 96% specific for GBS colonization at delivery [15], that the percentage of newborns who would be colonized with GBS without administration of IAP was 50%, and that the incidence of EOGBSD was 5.1–10 per 1000 live births depending on absence or presence of risk factors [16], we estimated the anticipated number of EOGBSD who were born to women with negative results of prenatal GBS screening in the public hospitals and Maternal and Child Health Centers, and then compared with the observed numbers.

Numbers of anticipated false negative (lower) = Number of women with screen negative results × (1–0.96) × 0.5 × 0.0051.

Numbers of anticipated false negative (higher) = Number of women with screen negative results × (1–0.96) × 0.5 × 0.01.

Assuming that the percentage of newborns who would be colonized with GBS without administration of IAP was 50%, that the incidence of EOGBSD was 5.1–10 per 1000 live births depending on absence or presence of risk factors [16], and that the effective of four or more hours of IAP was 90% in the prevention of EOGBSD [17], we estimated the anticipated number of EOGBSD who were born to women with GBS colonization and administration of IAP, and then compared with the observed number.

Numbers of anticipated failed IAP (lower) = Number of maternal GBS colonization $\times 0.5 \times 0.0051 \times (1–0.9)$.

Numbers of anticipated false negative (higher) = Number of maternal GBS colonization $\times 0.5 \times 0.01 \times (1– 0.9)$.

Results

GBS screening

During the 3-year period, the total number of antenatal GBS screening performed was 113,989 of which 74,419 (65.3%) in the Hospital Authority, and 43,171 (34.7%) in Maternal and Child Health Centers (Table 1).

The mean maternal GBS colonization rate was 21.8% (Table 1). The colonization rate was higher when the screening was performed in the Hospital Authority than the Maternal and Child Health Centers (23.7% vs 18.1%, $p < .001$). The colonization rate in the present universal screening program in 2012–14 was higher than the pilot study in 2009–10 (21.7% vs 9.6%, $p < .001$).

Screening and IAP rates

Of 47,427 pregnant women attended Maternal and Child Health Centers between 1 January 2012 and 31 December 2014, 7647 (16.1%) were excluded from the screening because of (a) previously affected infant (98), (b) GBS bacteriuria or known colonization before 35 weeks in the current pregnancy (901), or (c) GBS screening already performed in another place (6648). Of 39,780 pregnant women eligible for screening, 110 (0.3%) declined screening, and 100 (0.3%) were screened outside the recommended gestation (35–37 weeks). Similar screening data were not collected in the public hospitals as women's acceptance to the screening was found to be high in our previous pilot study [13].

In the first six months of 2012, IAP was given in 88.1% of colonized women. For the remaining 11.9%, IAP was not given because of an elective Caesarean section without preceding labour, the unavailability of a colonized result before delivery or a rapid progress of labour to delivery. There were no deviations from our protocol. Compliance check was not conducted afterwards.

EOGBSD

The total number of births during the 3-year period was 122,139. There were 29 cases of EOGBSD, and its incidence was 0.24 per 1000 births (Table 1). Of these 29 cases of EOGBSD, 25 had GBS isolated in the blood alone, one in the cerebrospinal fluid alone, and three in both the blood and cerebrospinal fluid.

Compared with the historical incidence of EOGBSD when the clinical risk-based screening strategy was used in all the public hospitals in Hong Kong [13], the incidence was significantly reduced by 75% after the implementation of universal swab-based screening (1 vs 0.24 per 1000 births, $p < .001$). The historical data [13] were generated from the same clinical information system on the same populations as in the present study.

Not surprisingly, the incidence of EOGBSD was higher in the preterm infants than the term infants (0.61 per 1000 vs 0.23 per 1000 live births), but 86.7% of the EOGBSD occurred in the term infants (Table 2). The main contributing factors to the latter included a

Table 1. Maternal group B streptococcus (GBS) colonization, and neonatal early onset GBS disease in the public health care system of Hong Kong territory from 2012 to 2014. Figures are *n* (%).

	2012	2013	2014	Total
Mothers screened				
Total number of GBS screening	38,799	35,863	39,327	113,989
GBS screening in HA	24,396 (62.9%)	23,713 (66.1%)	26,310 (66.9%)	74,419 (65.3%)
GBS screening in MCHCs	14,403 (37.1%)	12,150 (33.9%)	13,017 (33.1%)	39,570 (34.7%)
GBS colonization				
Overall GBS colonization	8379 (21.6%)	7732 (21.6%)	8722 (22.2%)	24,833 (21.8%)
GBS colonization in HA	5793 (23.7%)	5649 (23.8%)	6231 (23.7%)	17,673 (23.7%)
GBS colonization in MCHCs	2586 (18.0%)	2083 (17.1%)	2491 (19.1%)	7160 (18.1%)
Total number of live births in HA	44,871	37,074	40,194	122,139
Number of EOGBSD	8	11	10	29
EOGBSD (per 1000 live birth)	0.18	0.3	0.25	0.24

HA: hospital authority; MCHC: Maternal and Child Health Center; EOGBSD: early onset GBS disease.

Table 2. Characteristics of mothers whose infants had early onset group B streptococcal disease (EOGBSD) in all public hospitals of Hong Kong from 2012 to 2014. Figures are *n* (%).

Characteristics	Mothers whose infants had EOGBSD ($N = 29$)
Preterm (<37 weeks' gestation)	4 (13.8%)
Term (≥37 weeks' gestation)	25 (86.2%)
Not screened	6 (20.7%)
Non-booked, Non-Hong Kong citizen	3 (10.4%)
Defaulted	3 (10.4%)
Screened	19 (65.5%)
Positive for GBS	7 (24.1%)
Results available and IAP given	3 (10.3%)
Results not available during labour	4 (13.8%)
Negative for GBS	12 (41.3%)
In public hospitals	9 (31.0%)
In Maternal and Child Health Centers	2 (6.9%)
Outside Hong Kong	1 (3.5%)

false negative screening result (41.3%), lack of screening (20.7%) and an unavailability of a colonized result at labour (13.8%) (Table 2).

Of 12 screen negative cases with EOGBSD or false negative cases, nine were screened in the public hospitals and two in the Maternal and Child Health Centers (Table 2). In one case, screening was performed at 34 weeks' gestation (before 35 weeks) and the mother delivered at 39 weeks. In another case, screening was performed at 35 weeks' gestation, and delivery occurred at 41 weeks or more than 5 weeks after the screening. Using the assumptions and equations mentioned in section "Materials and methods", we estimated there would be 6–10 false negative cases of EOGBSD after screening in the public hospitals and 3–6 cases in Maternal and Child Health Centers, which were similar or greater than our observed numbers (9 and 2 after screening in the public hospitals and Maternal and Child Health Centers, respectively).

Of six mothers without screening (Table 2), half were non-Hong Kong citizens with inadequate prenatal care. Of four cases in which a positive GBS result was not available at labour, three occurred in the first year of the study, and only one in the subsequent two years after an improvement of reporting (Table 2).

EOGBSD occurred in four cases despite IAP was given for maternal GBS colonization according to the CDC guidelines 2010 [1]. Using the assumptions and equations mentioned in section "Materials and methods", we estimated there would be 6–13 cases of EOGBSD related to failure IAP, which were larger than our observed number (4).

Discussion

Consistent with the previous studies [18,19], the results of the present study showed that the incidence of EOGBSD decreased by 75% to 0.24 per 1000 live births after the implementation of the universal antenatal culture-based screening program and IAP to the colonized women. We believe that the success of our program was related to a collaborated effort by both public hospitals and Maternal and Child Health Centers, various professionals including obstetric doctors, midwives/nurses, microbiologists and laboratory personnel. Besides, conducting a pilot project to work out the logistics before full implementation, use of a standard protocol, counselling information and logistic workflow were likely important.

In the present study, the mean maternal GBS colonization rate was 21.8% which was more than twice than that in the pilot study [13] and another local study [20], probably because of the improvement in the collection and transport of specimen, and laboratory testing [11,12] rather than an increase in colonization rate over years. In our pilot study, the maternal GBS colonization rate was increased from 4.2% in the first month to 9.5% in the subsequent 11 months after improvement by combined efforts [13]. The mean colonization rate in the present study was higher than a recent review (17.9%) and the South East Asia (11.1%) [21].

Maternal GBS colonization rate was lower when the screening was performed in the Maternal and Child Health Centers than in the public hospitals. We postulate this result was probably related to the difference in maternal characteristics [20] and pregnancy risk [21] rather than the standard of taking, processing and culture of rectovaginal swabs between these two organizations. Since only the low risk pregnant women were shared care between Maternal and Child Health Centers and the public hospitals according to our agreed protocols, the former screened only the low risk pregnant women while the public hospitals screened both the low and high risk pregnant women. Besides, the observed false negative rates in these two organizations were not higher than the expected rates, and the proportion of screening outside the recommended gestation ages was small (0.4%). It seemed that the standard of screening was high in both organizations.

Like the previous studies [11,12,22], although the incidence of EOGBSD was reduced, the remaining problems included preterm deliveries, lack of screening, unavailability of GBS screening results, failure of IAP, and most importantly false negative screening. The latter contributed to as many as 40% of EOGBSD in term newborns. Prenatal screening may be more efficient if performed intrapartum than at 35–37 weeks' gestation [23]. Antenatal education on the

importance of GBS screening should be strengthened to improve the compliance rate. Improvement in IAP by an early administration and a correct choice of antibiotic for women with a penicillin allergy, particularly along preterm deliveries, can reduce EOGBSD [11,17]. In women with a penicillin allergy but at low risk for anaphylaxis, CDC guidelines 2002 recommended using cefazolin instead of clindamycin [14]. In the future, development of rapid intrapartum testing using molecular assays for GBS [24,25] and maternal GBS vaccine [5,26] may help further reduce the burden albeit with their own limitations.

At present, universal swab based screening and IAP to colonized women continue to be the main and a cost-effective strategy for the prevention of EOGBSD [1,27]. Monitoring the maternal GBS colonization and EOGBSD rates allowed us to calculate the expected false negative, and failed IAP numbers using the assumptions and equations mentioned in section "Materials and methods" [11,12]. By comparing the observed and expected maternal GBS colonization rate, false negative, and failed IAP numbers, we can assess the performance of a culture-based screening program.

The present study of more than 113,000 patients was large, involving all public hospitals with obstetric services and Maternal and Child Health Centers in Hong Kong, and using universal culture-based screening with the same protocol for three years. Since it was a retrospective study, we did not collect in all cases the data for errors in prenatal screening, laboratory methods, communication of results, and IAP. But, we believe that these issues were small as the maternal colonization rate was higher than previously reported, and the observed false negative rates and failed IAP numbers were not higher than the expected rates. Besides, we did not investigate if the incidence of EOGBSD varied with the colonization rates in different hospitals. In a previous review, it was found that the heterogeneity in colonization was unlikely to completely explain geographical variation in the incidence of EOGBSD [21]. We also did not select a control group for comparison with the cases of EOGBSD. A randomized controlled trial or case controlled study is required for further investigation. During the study period, there were no major changes in obstetric practice including routine use of intrapartum antibiotics.

In conclusion, maternal GBS colonization rate was higher than previously reported. It appeared that the colonization rate differed between higher and lower pregnancy risk populations rather than the standard of culture methods between the public hospitals and Maternal and Child Health Centers. The incidence of EOGBSD decreased after implementation of universal antenatal culture-based screening program. The remaining problems included false negative screening results, lack of screening, and unavailability of screening results at labour.

Acknowledgements

The authors would like to thank the Government of HKSAR for the support on implementing the Culture-based Universal Prenatal Screening Programme for Group B Streptococcus (the Programme) and all colleagues of the Department of Health and the Hospital Authority for the collaboration and contributions to the Programme.

Disclosure statement

The authors report no conflicts of interest.

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