ORIGINAL ARTICLE

The accuracy and influencing factors for preference of self-sampling in group B streptococcus screening: a cross-sectional study

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ABSTRACT

Objective: Self-sampling with proper instruction in 35–37 weeks gestation is an option to clinician sampling to prevent early-onset invasive group B streptococcal disease of infants. We aimed to assess the accuracy of self-sampling and influencing factors of preference for collection method in Chinese women.

Methods: We compared the screening results of self-sampling with clinician collection in a sample of 520 women in late pregnancy. We collected their demographics, clinical information and preference for collection method. A multi-nominal logistic regression model was used to measure the association between the influencing factors and these participants’ preference.

Results: A good agreement between the two collection methods was found with a Cohen’s Kappa coefficient 0.83 (95% CI = 0.71–0.95). The prevalence of GBS infection in the two methods is statistically different in this low-risk group when self-sampling presented a better outcome in terms of detecting positive cases. Self-sampling is preferable by 20.9% of the participants. No less pain during self-sampling and age older than 35 years old was statistically related to preference for clinician collection.

Conclusion: The accuracy of self-sampling is no worse than clinician collection. It could be an option for those younger than 35 years old, especially for those who report low pain threshold. Pregnant women are able to collect rectovaginal samples prior to their antenatal visit. Self-sampling followed by appropriate transportation of the sample to an advanced laboratory could eliminate the effects of local laboratory capacity. There are implications in increasing GBS screening participation in resource-limited settings.

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INTRODUCTION

Group B streptococcus (GBS) is the leading cause of early-onset (newborns younger than 7 days) neonatal sepsis in the US [1]. Vertical transmission from mother at the time of delivery is the primary risk factor for neonatal infection. Antepartum screening for GBS colonization and the use of intrapartum antibiotics (IAP) led to a significant reduction in the incidence of early-onset GBS [1]. In 2010, the US Centers for Disease Control and Prevention (CDC) recommended universal culture-based screening of all pregnant women at 35–37 weeks’ gestation, and women tested positive should receive intrapartum treatment. In accordance with the CDC protocols, clinicians collect a swab at the lower vagina and anorectum, followed by incubation onto selective broth media [2]. Self-sampling with proper instruction is an option to clinician sampling [3]. Previous studies validated the accuracy of self-sampling in terms of equivalent detection rate and sensitivity [4,5]. However, Molnar and colleagues reported that GBS self-sampling was less acceptable in non-north American women [6]. There were recent debates raised by Taiwan obstetricians on local pregnant women’s acceptability of self-sampling in Hong Kong [7,8]. They argued that pregnant women would not prefer a complicated self-collection procedure. Moreover, the self-sampling screening result is questionable for their low adherence to the method of swab collection because even obstetricians perform nonstandard sampling on perianal skin rather than rectovaginal site [7].

Given the participants in the Hong Kong study reported their preference in their next pregnancy and no participant had done self-sampling, evidence on the accuracy and acceptability of self-sampling in GBS
screening in the Chinese population was lacking. Therefore, this study aims to examine: (1) the accuracy of self-sampling compared to clinician collecting sample in GBS screening, and (2) the preference for collection method and its influencing factors.

Materials and methods

Study setting

The study was conducted in the antenatal outpatient clinic of a tertiary hospital for women and children health in Shenzhen from June to September of 2019. This hospital provides comprehensive antenatal and intrapartum care. The annual delivery volume is about 20,000 births. A trained midwifery explained the study to pregnant women at their 35–40 week's gestation and obtained the written informed consent of those interested in participation. The research team offered a free-of-charge self-collected GBS screening test to the participants if they had GBS screening done by a clinician before. Two samples may be taken at different visits. The midwifery would follow a standard written diagram and explain how to collect a rectovaginal swab to these participants. The same instruction was pasted on the wall of washrooms where these participants completed the sampling. After submitting the samples, the participants needed to complete a questionnaire on their preference and demographics. GBS cultures were processed by the lab physicians who were blind to collection methods. When the culture tested positive, a repeated test and a drug sensitivity test would be done in line with a standard protocol. The obstetricians would provide intrapartum treatment when any sample tested positive. This study was approved by the Ethics Review Committee of the hospital.

Sample size

We estimated the sample size based on a previous study done by the same team in 2017. After a training course on collection procedure among the obstetricians, the prevalence of maternal GBS colonization increased from 11% to 17% [9]. We assume self-sampling is no better than clinician collection before training sessions. The hypothesis was that the two collection methods were equal in detecting positive cases. A sample size of 522 subjects is needed to rule out such a difference in prevalence with a type 1 error rate of 5% (2-tailed), and a power (1-β) of 80% [10].

Data collection

The screening test result was binary. We assessed the participants' demographics, clinical information and self-reported pain level during collection. Self-reported pain level was measured with a scale from 1 to 10 indicating an increasing level of pain. Pain difference is defined as a categorical variable by comparing self-reported pain levels of the two collection (more pain during self-sampling, equal, and more pain during clinician collection). The maternal demographics included age (<35 years, and ≥35 years) and education attainment (≤12 years, college or university, and postgraduate). Their clinical information included parity (primipara, multipara), gestational age (<37 week, ≥37 week) and previous vaginal suppository use (yes or no). The outcome measure is participants' preference for collection method among three options: self-sampling, no preference, and clinician collection.

Statistical analysis

We analyzed the screening result using the Paired McNemar Test. A multi-nominal logistic regression model was then used to measure the association between maternal age, education attainment, parity, gestational age, previous vaginal suppository use, pain difference, and preference for collection method. Data were analyzed using SPSS version 23 (SPSS Inc., Chicago, IL).

Results

There were 520 women who did both self-sampling and clinician sampling, among whom 2 did repeated self-sampling. These two participants’ screening results were both negative in self-sampling and clinician sampling. Therefore, there are 522 self-sampling test results in total. 7 self-sampled positive cases were tested negative in clinician samples while no negative self-samples tested positive in clinician collection. There are 18 cases tested both positive and 497 cases tested both negative in the two collection methods. The Cohen’s Kappa coefficient is 0.83 (95% CI = 0.71–0.95), indicating a good agreement between the two collection methods. However, the prevalence of GBS infection in self-collected samples is statistically different (Paired McNemar’s chi-square, exact test = 5.14, p = .0156) from that in clinician collected samples with a difference of 1.35% (95% CI = 0.36–2.34%). The prevalence of self-sampling is 4.8% while it is 3.45% for clinician sampling. Self-sampling presented a
higher detection rate than clinician sampling although the prevalence is quite low in this population.

We completed 522 questionnaires. There were more than 3 missing values in 1 questionnaire. Therefore, data in 521 valid questionnaires were used for analysis. The mean maternal age was 30.2 years with a range from 20 to 43 years old. Most (85.2%) were non-elderly parturient women (maternal age < 35 years old). The gestational age at testing ranged from 35 to 40 weeks. 179 women did self-sampling before 37th gestation week. 307 (58.9%) women were primipara. 243 women (46.6%) used vaginal suppositories before. 82 (15.8%) women’s education attainment were ≤12 years, 415 (79.7%) received college or university degree and 24 (4.6%) had post-graduate education. The participants’ self-reported pain level for self-sampling ranged from 1 to 3 while 9 women reported pain level higher than a scale of 4 during clinician collection. Of these participants, 62 (11.9%) reported more pain during self-sampling, 357 (68.5%) reported equal level and 102 (19.6%) for clinician collection. 109 (20.9%) women preferred self-sampling, 279 (53.6%) had no preference, and 132 (25.3%) preferred clinician collection.

Table 1 presents the association between these variables and preference with preferring clinician collection as the reference category in the unadjusted multi-nominal logistic regression model. Gestational age and previous vaginal suppository use were not statistically associated with preference for collection methods. Lower education attainment women were more likely to show no preference for collection methods compared with clinician collection, although the association was not statistically significant for preferring self-sampling (p value = .065). Therefore, four variables including education attainment were included in the final model.

Results from the fully adjusted model (Table 2) suggest that non-elderly parturient women were 2.84 (95% CI = 1.19–6.74) times more likely to prefer self-sampling compared to clinician sampling, adjusting for parity, education and pain difference. These participants who experienced more or equal pain during self-sampling compared to clinician collection were more likely to prefer clinician sampling controlling the other three factors’ effect. Those primipara were 1.65 (95% CI = 1.04–2.59) times more likely to show no preference relative to clinician collection adjusting for maternal age, education and pain difference. After adjustment for maternal age, parity, and pain difference, less educated women (≤12 years and college or university) were more likely to show no preference (vs clinician collection) than women with graduate degree.

### Discussion

Our study found a high agreement between the two collection methods in this relatively low-risk sample. Few participants reported their obstetricians collected vaginal instead of rectovaginal swab. Another substandard way of performing sampling on perianal skin when a pelvic examination would otherwise be required was reported in Taiwan [7]. Providing

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**Table 1.** Association between six variables and preference for collection method in unadjusted models.

| Variable                      | n       | Self-sampling | No preference | Clinician-sampling | p value<sup>a</sup> |
|-------------------------------|---------|---------------|---------------|--------------------|--------------------|
| Maternal age<sup>b</sup>      |         |               |               |                    |                    |
| < 35 years                    | 443     | 101(22.8%)    | 237(53.5%)    | 105(23.7%)         | .012               |
| ≥35 years                     | 77      | 85(10.4%)     | 42(54.5%)     | 27(35.1%)          |                    |
| Gestational age<sup>c</sup>   |         |               |               |                    | .603               |
| < 37 week                     | 178     | 33(18.5%)     | 98(55.1%)     | 47(26.4%)          |                    |
| ≥37 week                      | 314     | 76(22.3%)     | 180(52.8%)    | 85(24.9%)          |                    |
| Parity<sup>b</sup>            |         |               |               |                    | .033               |
| Primipara                     | 306     | 72(23.5%)     | 168(54.9%)    | 66(21.6%)          |                    |
| Multipara                     | 214     | 37(17.3%)     | 111(51.9%)    | 66(30.8%)          |                    |
| Vaginal suppository use<sup>d</sup> | |     |               |                    | .219               |
| No                            | 275     | 65(23.6%)     | 140(50.9%)    | 70(25.5%)          |                    |
| Yes                           | 242     | 43(17.8%)     | 138(57.0%)    | 61(25.2%)          |                    |
| Education<sup>b</sup>         |         |               |               |                    | .065               |
| ≤ 12 years                    | 82      | 15(18.3%)     | 47(57.3%)     | 20(24.4%)          |                    |
| College or university         | 414     | 86(20.8%)     | 226(54.6%)    | 102(24.6%)         |                    |
| Post graduate                 | 24      | 8(33.3%)      | 6(25%)        | 10(41.7%)          | <.001              |
| Pain difference<sup>b</sup>   |         |               |               |                    |                    |
| More pain during self-sampling| 62      | 14(22.6%)     | 21(33.9%)     | 27(43.5%)          |                    |
| Equal                         | 356     | 59(16.6%)     | 215(60.4%)    | 82(23.0%)          |                    |
| More pain during clinician collection | 102 | 36(35.3%) | 43(42.2%) | 23(22.5%) | |

<sup>a</sup>Reference category: preference for clinician sampling.

<sup>b</sup>1 missing value.

<sup>c</sup>2 missing values.

<sup>d</sup>4 missing values.
standard collection in line with the CDC guideline is an important move for quality assurance of GBS screening. Pregnant women pay careful attention to their babies’ health and the impact of their health status on their babies. If instructed properly, they could be able to complete the collection by themselves. Self-sampling also facilitates pregnant women’s involvement in obstetric care, which may improve GBS screening with high efficiency and reduced cost for women could collect their rectovaginal sample at home just prior to their antenatal check. Self-sampling was preferable by 20.9% of the participants. Inconsistent preferences were reported in earlier studies [4,11,12]. Moreover, 25.3% women preferred clinician collection, which is consistent with Molnar’s findings [6]. When the use of self-sampling is more prevalent in sexually transmitted disease prevention and cervical screening in recent years, an increasing number of Chinese women are receptive to this collection due to increased autonomy in health improvement [13].

We also found that self-sampling presented a higher detection rate than clinician collection. It may result from participants’ better collection performance than clinicians. On the other hand, the difference in collection times could explain in part the differing detection rates in the two groups because maternal GBS colonization is transient with varying prevalence and serotype-specific acquisition rates during pregnancy [14]. Self-sampling were collected later than the obstetrician swabs, women may become colonized in the interim period between the two collections [15]. There were 126 women conducting self-sampling at the same visit. The median of the interval is 14 days. We were unable to rule out this confounding effect in the comparison of the two tests without examining the relationship between the interval and discordance.

Individual patient preferences can be considered with influencing factors. Our study found factors influencing women’s preference included maternal age, parity, education attainment, and pain difference. Different from findings that younger women were more likely to prefer clinician collection in Molnar’s study, our study found that younger women were more likely to prefer self-sampling [6]. Molnar and colleagues also reported that lower socioeconomic status women were less comfortable with self-care, but less-educated women in this study were more likely to show no preference relative to clinician collection than women with graduate education. No less pain during self-sampling was related to preference for clinician collection. Therefore, self-sampling could be an option for those younger than 35 years old, especially for those who report low pain threshold.

The strengths of our study include a large sample size and adjustments in the multi-nominal regression model to rule out confounding effects. However, there are limitations. First of all, there were 2 women who had two self-sampling tests and completed two questionnaires. The cultural results of these two women were both negative in the two collection methods. It would not influence the statistical test result, but we cannot get rid of these two questionnaires because of anonymous recruitment. Secondly, the participants conducted self-sampling after their usual screening by clinicians, new infection may occur between the two tests. Further, the prevalence of GBS colonization is low in this population. Women tested negative in previous screening were more likely to take part in the study while those tested positive already were not likely to do the same test again. Last but not the least,
clinician sampling had been done before most participants completed the questionnaire so these women could remember less the intensity of pain when clinicians sampled several weeks ago. Future research should use a cohort study to focus on a comparison of the two collection methods in real-world setting.

Conclusion
Our study suggests high agreement between the two collection methods. If instructed properly, pregnant women are able to collect rectovaginal samples prior to their antenatal visit. Self-sampling is preferable by 20.9% of the participants. It could be an option for those younger than 35 years old, especially for those who report low pain threshold. Also, self-sampling followed by appropriate transportation of the sample to an advanced laboratory could eliminate the effects of local laboratory capacity. There are implications in increasing GBS screening participation in resource-limited settings to facilitate individualized care of universal GBS screening to prevent early-onset neonatal GBS disease.

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Disclosure statement
No potential conflict of interest was reported by the author(s).

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Data availability statement
The datasets generated and analyzed for the current study are available from the corresponding author on reasonable request.

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