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

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# Abstract

Background

Self-sampling with proper instruction in 35-37 weeks' gestation is supplementary to clinician sampling to prevent early-onset invasive group B streptococcal disease of infants. Despite of the accuracy proved in previous studies, disputes were raised on pregnant women's low preference and adherence to the method of swab collection. We aimed to assess the accuracy of self-sampling and influencing factors for preference on collection method in Chinese women.

Methods

We compared screening results of self-sampling with clinician collection in a sample of 522 women in late pregnancy. These participants needed to complete a questionnaire on their preference and demographics after self-sampling. A multi-nominal logistic regression model was then used to measure the association between the influencing factors and preference for collection method.

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. Four factors (maternal age, parity, education attainment and pain difference) were included in the final multi-nominal regression model while gestational age and vaginal suppository use were excluded. 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. If these participants experienced more or equal pain during self-sampling compared to clinician collection, they were more likely to prefer clinician sampling controlling the other three factors' effect.

Conclusions

Our study suggests high agreement between the two collection methods. Self-sampling presented a higher detection rate than physician-collected samples. Pregnant women are able to collect rectovaginal samples prior to their antenatal visit. Self-sampling is preferable by 1/5 of the participants and it could be an option for those younger than 35 years old, especially for those with low pain threshold.


# Background

Antenatal screening for Group B Streptococcus (GBS) colonization is an important measure to prevent early-onset (babies younger than 7 days) invasive disease. If rectovaginal culture is positive, the use of intrapartum antibiotics prophylaxis (IAP) could reduce the incidence thereby neonatal morbidity and mortality caused by sepsis, pneumonia, and meningitis (1). In the guideline from the US Centers for Disease Control and Prevention on universal screening at 35 to 37 weeks' gestation, clinicians collect a swab at the lower vagina and anorectum, followed by incubation onto selective broth media (2). Self-

sampling with proper instruction is supplementary 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 disputes raised by Taiwan obstetricians on the findings of a study examining local pregnant women's acceptability 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, even obstetricians perform sampling on perianal skin rather than rectovaginal site.

Given the participants in the Hong Kong study reported their preference in their next pregnancy and no one had self-sampling, evidence on the accuracy and acceptability of self-sampling in GBS screening in 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 on collection method and its influencing factors.

# Methods

Study setting

We approached pregnant women at their 35–40 week's gestation in the antenatal outpatient clinic of a tertiary hospital for women and children health in Baoan district of Shenzhen, China. This hospital provides comprehensive antenatal and intrapartum care. The annual delivery volume is about 20000 births. A trained clinic receptionist explained the study to all potential participants and obtained their written informed consent. The research team offered a free-of-charge GBS screening test to the participants with their self-collected sample if they had such screening done by a clinician before. The receptionist 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 washroom where these participants completed the sampling procedure. After submitting the samples, the participants needed to complete a questionnaire on their preference and demographics. The self-collected samples would be handled and tested by the lab physicians who were blind of collection methods. If culture testing positive, a repeated test and a drug sensitivity test would be done in line with a standard protocol. The obstetricians would use IAP no matter which sample indicated the positive result. The participants could check the test result through a particular application in their cellphone. 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 11–17% (9). 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). Assuming self-sampling is no better than clinician collection before training sessions, the maximum size of sample should be 522.

Data collection

The screening test result was binary. In the questionnaire, the maternal demographics included age and education attainment. Their clinical information including parity, gestational age, vaginal suppository use before, and self-reported pain level of different sampling method with a scale from 1 to 10. We defined pain difference as a categorical variable: more pain for self-sampling, equal, and more pain for clinician collection. We interviewed participants' preference for collection method among three options: self-sampling, no preference, and clinician collection.

Statistical analysis

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

# Results

There were 526 self-collected samples in total. 520 participants did both self-sampling and clinician sampling, among whom 2 did repeated self-sampling. The screening results are shown in Table 1.

Table 1
Self-sampling versus clinician collection result in 522 pairs

| | | clinician collection | |
|---|---|---|---|
| | | + | - |
| self-sampling | + | 18 | 7 |
| | - | 0 | 497 |

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 = 0.0156) from that in clinician collected samples with a difference of 1.35% (95% CI 0.36%-2.34%).

We completed 526 questionnaires. We excluded 4 women because they did GBS screening for the first time. There were more than 3 missing values in 1 questionnaire. Therefore, data in 521 valid questionnaires were used for analysis. The mean of 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 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 for clinician sampling. Of these participants, 62 (11.9%) reported more pain for 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 2 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 vaginal suppository use before were not statistically associated with preference on collection methods. Lower education attainment women were more likely to show no preference for collection methods compared with clinician collection, although education was not statistically significant for preferring self-sampling (P value = 0.065). Therefore, four variables including education attainment were included into the final model.

Table 2
Association between six variables and preference in unadjusted model

| Variable | n | Self-sampling | No preference | Clinician collection | P value |
|---|---|---|---|---|---|
| Maternal age [a] | | | | | 0.012 |
| 35 years | 443 | 101(22.8%) | 237(53.5%) | 105(23.7%) | |
| ≥35 years | 77 | 8(10.4%) | 42(54.5%) | 27(35.1%) | |
| Gestational age [b] | | | | | 0.603 |
| 37 week | 178 | 33(18.5%) | 98(55.1%) | 47(26.4%) | |
| ≥37 week | 341 | 76(22.3%) | 180(52.8%) | 85(24.9%) | |
| Parity [a] | | | | | 0.033 |
| Primipara | 306 | 72(23.5%) | 168(54.9%) | 66(21.6%) | |
| Non primipara | 214 | 37(17.3%) | 111(51.9%) | 66(30.8%) | |
| Vaginal suppository use [c] | | | | | 0.219 |
| No | 275 | 65(23.6%) | 140(50.9%) | 70(25.5%) | |
| Yes | 242 | 43(17.8%) | 138(57.0%) | 61(25.2%) | |
| Education [a] | | | | | 0.065 |
| ≤ 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%) | |
| Pain difference [a] | | | | | 0.001 |
| More pain for 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 for clinician collection | 102 | 36(35.3%) | 43(42.2%) | 23(22.5%) | |
| a 1 missing value | | | | | |
| b 2 missing values | | | | | |
| c 4 missing values | | | | | |

Results from the fully adjusted model 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. If these participants experienced more or equal pain during self-sampling compared to clinician collection, they 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 that self-sampling presented a better outcome in terms of detecting positive cases for the prevalence difference of the two collection methods is statistically significant. In earlier studies on the accuracy of self-sampling, it was proved as effective or sensitive as clinician sampling. A plausible explanation is that participants in this sample were more likely to perform standard collection than their clinicians. Some participants reported their obstetricians collected vaginal samples only, rather than collecting a rectovaginal swab. Another substandard way of performing sampling on perianal skin when a pelvic examination would otherwise be required was reported in Taiwan. Providing standard collection in line with the CDC guideline is an important move for quality assurance of GBS screening. Pregnant women pay careful attention to the health of their babies and the impact of their health status on their babies. If instructed properly, they could be able to complete the collection by themselves. Therefore, self-sampling as a form of involvement in obstetric care may improve the quality of 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 about 1/5 of participated women. Inconsistent preferences were found in earlier studies (4, 11, 12). Moreover, 25.3% women preferred clinician collection, which is consistent with Molnar' 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 is receptive to this collection due to increased autonomy in health improvement (13).

Individual patient preferences can be considered with influencing factors. In our study, factors influencing women's preference included maternal age, parity, education attainment, and pain difference. These are important to facilitate clinical practice for universal screening. Different from findings that younger women and those who had GBS screening done in previous pregnancy 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). Pain during collection compared with clinician sampling was also important to influence the preference of these women on self-sampling. 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. Therefore, self-sampling could be an option for those younger than 35 years old, especially for those with low pain threshold.

The strengths of our study include a large sample size and adjustments in multi-nominal regression models 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 culture result of these two women were negative in both collection methods. It would not influence the statistical test result. Because of anonymous recruitment, we cannot get rid of these two questionnaires. 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 with a negative result in previous screening were more likely to take part in the study while those with a positive result already were not likely to do the same test again. Future research could focus on a comparison of the two collection methods in real-world setting using a cohort study.

# Conclusions

Our study suggests high agreement between the two collection methods. Self-sampling presented a higher detection rate than physician-collected samples. If instructed properly, pregnant women are able to collect rectovaginal samples prior to their antenatal visit. Self-sampling is preferable by 20% of the participants. It could be an option for those younger than 35 years old, especially for those with low pain threshold to facilitate individualized care of universal GBS screening to prevent early-onset neonatal GBS disease.

# Abbreviations

CI: confidence interval; GBS: group B streptococcus; IAP: intrapartum antibiotics prophylaxis

# Declarations

### Ethics approval and consent to participate

The written informed consent of all participants was obtained before participating the study. Ethical approval was obtained from the Ethics Review Committee of Shenzhen Baoan Women's and Children's Hospital.

### Consent for publication

Not applicable.

### Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

### Competing interests

The authors declare that they have no competing interests.

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### Authors' contributions

RC and LW did study design. FM and XC contributed in data acquisition. RC conducted data analysis and interpretation and manuscript drafting. LW and YZ did quality control of the screening. All authors read, reviewed and approved the final manuscript.

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## References

1. Kwatra G, Cunnington MC, Merrall E, Adrian PV, Ip M, Klugman KP, Tam WH, Madhi SA. Prevalence of maternal colonisation with group B streptococcus: a systematic review and meta-analysis. Lancet Infect Dis 2016;16(9): 1076-1084.
2. Verani JR, McGee L, Schrag SJ. Prevention of perinatal group B streptococcal disease--revised guidelines from CDC. MMWR Recomm Rep 2010;59(Rr-10): 1-36.
3. American College of Obstetricians and Gynecologists Committee on Obstetric Practice. ACOG committee opinion no.485: prevention of early-onset group B streptococcal disease in newborns. Obstet Gynecol. 2011;117(4):1019-1027.
4. Price D, Shaw E, Howard M, Zazulak J, Waters H, Kaczorowski J. Self-sampling for group B streptococcus in women 35 to 37 weeks pregnant is accurate and acceptable: a randomized cross-over trial. J Obstet Gynaecol Can. 2006;28(12):1083-1088.
5. Hicks P, Diaz-Perez MJ. Patient self-collection of group B streptococcal specimens during pregnancy: J Am Board Fam Med. 2009;22(2):136-40.
6. Molnar P, Biringer A, McGeer A, Mclsaac W, the Mount Sinai GBS Screening Group. Can pregnant women obtain their own specimens for group B streptococcus? A comparison of maternal versus physician screening. Fam Pract. 1997;14(5):403-6.
7. Lee WL, Yeh CC, Wang PH. Did self-sampling improve the adherence to group B streptococci screening in pregnant women? J Chin Med Assoc. 2016;79(2):51-3
8. Ko JK, Yung SS, Seto MT, Lee CP. A questionnaire study on the acceptability of self-sampling versus screening by clinicians for Group B Streptococcus. J Chin Med Assoc. 2016;79(2):83-7.

9. Wu LJ, Wang FL, Zou JH, Yang J, Huang YE, Ming F, Chen XR, Chen RR, Zhu YF. Analysis of screening strategy of group B streptococcus in the third trimester and its influence on pregnancy outcome. Zhonghua Fu Chan Ke Za Zhi.2019;54(3):154-159
10. Sample Size Calculator: Two Parallel-Sample Proportions. https://www2.ccrb.cuhk.edu.hk/stat/proportion/tspp_equality.htm
11. Arya A, Cryan N, O'Sullivan K, Greene RA, Higgins JR. Self-collected versus health professional-collected genital swabs to identify the prevalence of group B streptococcus: a comparison of patient preference and efficacy. Eur J Obstet Gynecol Reprod Biol 2008;139:43–45
12. Torok PG, Dunn JP. Self-collection of antepartum anogenital group B streptococcus cultures. J Am Board Fam Pract. 2000;13:107-10.
13. Belinson JL, Wang G, Qu X, Du H, Shen J, Xu J, Zhong L, Yi J, Yi X, Wu R.The development and evaluation of a community based model for cervical cancer screening based on self-sampling. Gynecol Oncol. 2014;132(3):636-42.