

Self-Sampling for Group B Streptococcus in Women 35 to 37 Weeks Pregnant Is Accurate and Acceptable: A Randomized Cross-Over Trial

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Abstract

Objective: In Canada, screening for group B Streptococcus (GBS) in pregnant women is recommended at 35 to 37 weeks' gestation. Since there is normally no other indication for pelvic examination at this stage of pregnancy, women may be more comfortable performing the test themselves. We assessed the accuracy of self-sampling versus clinician sampling for GBS and women's preference for each collection method.

Methods: Consecutive patients presenting between October 2003 and April 2005 to a maternity centre in Hamilton for their 35- to 37-week prenatal visit were randomly allocated to having vaginal-rectal swabs self-collected, and then collected by a clinician, or to having the swabs clinician-collected, and then self-collected. The main outcomes were prevalence of infection and sensitivity of the two methods. Other analyses compared women who refused participation in the study with those who participated, and preference for sampling method before and after conducting the tests.

Results: Of the 386 women approached, 330 (85.5%) agreed to participate. The prevalence of GBS was 17.0% (56/330) and 18.8% (62/330) in the self-obtained and clinician-obtained specimens respectively (difference = 1.8%; 95% confidence intervals [CI] -2.0-6.0). Sensitivity was 87.5% (95% CI 77.0-93.8) and 96.9% (95% CI 88.7-99.8) for the self-obtained and clinician-obtained specimens respectively. Women who declined to participate in self-sampling were significantly more likely not to have completed high school and to prefer clinician sampling. Prior to testing, 79% of women preferred self-sampling or had no preference. Preference was unchanged for approximately two-thirds of women after sampling.

Conclusion: Self-sampling for GBS is an accurate and acceptable alternative for the majority of pregnant women. Less-educated women may be hesitant to self-sample, and clinician sampling should remain an option.

Key Words: Group B Streptococcus, pregnancy, self-sampling, accuracy

Competing Interests: None declared.

Received on April 26, 2006

Accepted on June 15, 2006

Résumé

Objectif : Au Canada, le dépistage du streptocoque du groupe B (SGB) chez les femmes enceintes est recommandé au cours de la période se situant entre la 35^e et la 37^e semaine de gestation. Puisqu'il n'existe habituellement aucune indication de procéder à un examen pelvien à ce stade de la grossesse, il est possible que les femmes soient plus enclines à effectuer ce dépistage elles-mêmes. Nous avons évalué la précision de l'autoprélèvement aux fins du dépistage du SGB à celle d'un prélèvement effectué par un clinicien, ainsi que les préférences des femmes quant à chacune de ces méthodes de prélèvement.

Méthodes : Des patientes se présentant consécutivement, entre octobre 2003 et avril 2005, à un centre de maternité de Hamilton pour leur consultation prénatale entre la 35^e et la 37^e semaine de gestation ont été affectées, au hasard, à un groupe devant procéder à des autoécouvillonnages vaginaux-rectaux, puis se soumettre à des prélèvements effectués par un clinicien, ou à un groupe devant se soumettre à des prélèvements effectués par un clinicien, puis procéder à des autoprélèvements. Les principaux critères d'évaluation étaient la prévalence de l'infection et la sensibilité des deux méthodes. D'autres analyses ont comparé les femmes ayant refusé de participer à l'étude à celles qui ont accepté de le faire, ainsi que les préférences quant au mode de prélèvement avant et après la tenue des tests.

Résultats : Des 386 femmes sollicitées, 330 (85,5 %) ont consenti à participer. La prévalence du SGB était de 17,0 % (56/330) et de 18,8 % (62/330) pour les autoprélèvements et les prélèvements effectués par un clinicien, respectivement (différence = 1,8 %; intervalle de confiance [IC] à 95 %, 2,0-6,0). La sensibilité était de 87,5 % (IC à 95 %, 77,0-93,8) et de 96,9 % (IC à 95 %, 88,7-99,8) pour les autoprélèvements et les prélèvements effectués par un clinicien, respectivement. Les femmes ayant refusé de procéder à l'autoprélèvement étaient plus susceptibles de ne pas avoir terminé leurs études secondaires et de préférer se soumettre à des prélèvements effectués par un clinicien. Avant le dépistage, 79 % des femmes préféraient l'autoprélèvement ou n'indiquaient aucune préférence. Cette préférence est demeurée la même chez environ deux tiers des femmes à la suite des prélèvements.

Conclusion : L'autoprélèvement aux fins du dépistage du SGB constitue une solution de rechange précise et acceptable pour la plupart des femmes enceintes. Les femmes ayant bénéficié d'une éducation moindre peuvent s'avérer hésitantes face à l'autoprélèvement; ainsi, l'option d'avoir recours à un clinicien pour effectuer les prélèvements devrait demeurer disponible.

J Obstet Gynaecol Can 2006;28(12):1083–1088

INTRODUCTION

Group B streptococcal (GBS) infection is a major preventable cause of neonatal morbidity and mortality.^{1,2} Transmission of the infection from mother to neonate occurs during vaginal birth. It is estimated that intrapartum chemoprophylaxis has reduced the incidence of early onset neonatal GBS disease from 2–3/1000 to 0.5/1000.³ The case fatality rate is approximately 4%.³ Rectovaginal colonization rates in pregnant women in North America range between 10% and 30%.^{2,4} Current North American screening recommendations advise rectovaginal sampling at 35 to 37 weeks' gestation and intrapartum antibiotic prophylaxis for women with a positive culture.^{3,5}

Self-sampling has been suggested as an alternative to clinician sampling and has been shown to be accurate and often preferable for sexually transmitted disease screening.⁶ Four previous studies have specifically compared GBS rectovaginal self-sampling with clinician sampling in pregnant women and have shown self-sampling to be generally acceptable and at least as accurate as clinician sampling.^{7–10} In two of these studies, sampling was done earlier in pregnancy than the present recommendations, at between 26 and 28 weeks^{8,9} or between 24 and 42 weeks of pregnancy.⁷ Three of the studies enrolled homogeneous populations of women with relatively high socioeconomic status,^{8–10} and the other study enrolled a primarily African-American population.⁷ None of the studies randomized the sequence of swab collection between clinician and patient. When sequential swabs are taken, it is possible that more of the organism will be present in the first swab, resulting in apparently better sensitivity of the first test method than subsequent methods. Some evidence suggests that sensitivity for detecting sexually transmitted infections with cervical swabs and brushes may decrease as serial specimens are taken.¹¹

Since there is currently no definitive evidence for the accuracy of vaginal-rectal self-sampling at 35 to 37 weeks' gestation, this study evaluated whether a self-collected rectovaginal swab for GBS was as effective in detecting infection as a clinician-collected swab. We also described women's preferences for and perceptions of sampling options before and after sampling, and we collected data on women who refused participation in order to estimate the acceptability of self-sampling.

METHODS

Participants and Setting

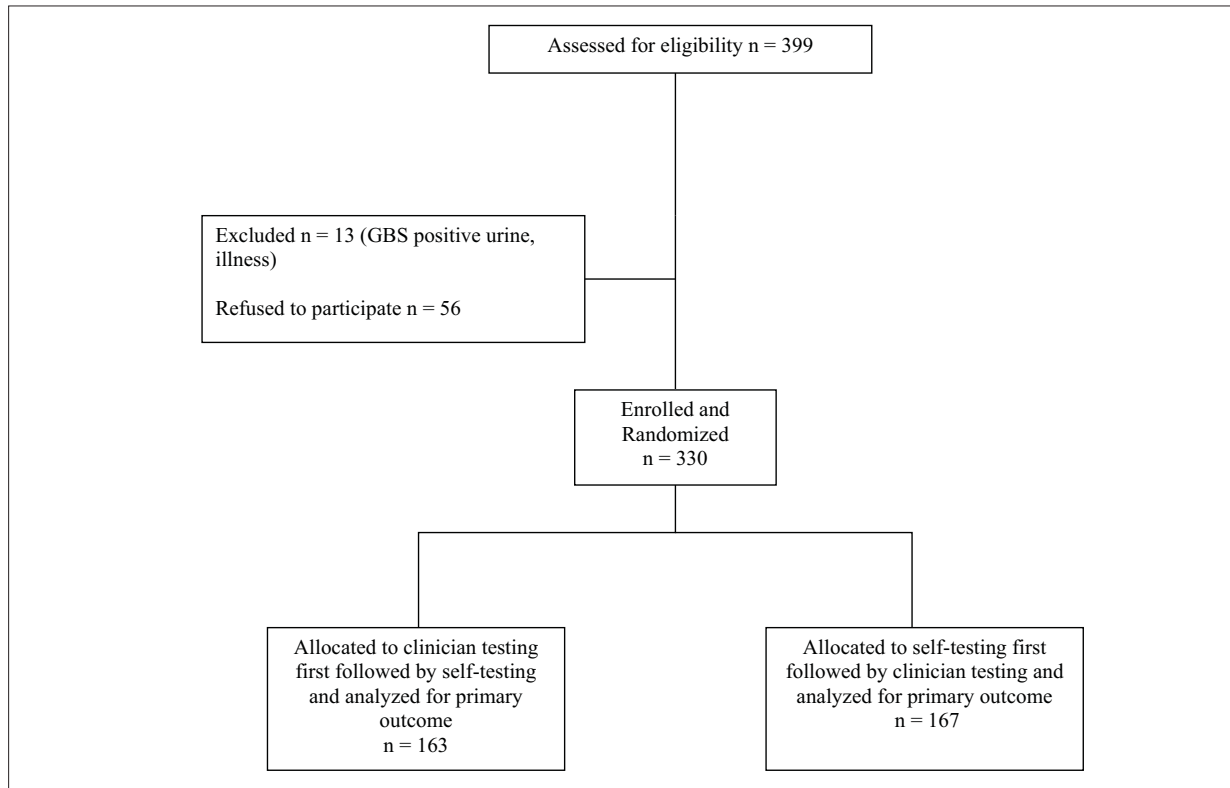
We approached consecutive patients presenting at 35 to 37 weeks' gestation to the Maternity Centre of Hamilton (MCH) between October 2003 and May 2005. All presenting women were eligible unless they had tested positive for GBS in their urine samples or could not understand English well enough to provide written informed consent. The MCH is a multidisciplinary primary maternity centre, affiliated with McMaster University's Department of Family Medicine and staffed by family physicians, midwives, nurse practitioners, and other allied health professionals, that provides comprehensive antenatal and intrapartum care. Women are referred to the MCH by their family physicians or local agencies, or are self-referred, and they usually receive care from one MCH physician and nurse practitioner throughout their pregnancy. They deliver at a nearby hospital (St. Joseph's Healthcare) under the care of the on-call MCH physician (except for patients of midwives who deliver at this hospital or at home), and they return with their infants to the care of their usual provider after birth. A detailed description of the MCH can be found elsewhere.¹²

Randomization and Intervention

When potential participants arrived for a scheduled visit, they were approached by a trained clinic receptionist who explained the study and obtained written informed consent. Participants were then randomized either to conduct self-sampling first, followed by clinician testing, or the reverse. We randomized the test sequence through computer-generated numbers. The allocation of test sequence was concealed from the clinic assistant using an opaque envelope. The clinic receptionist provided participants with simple written instructions and a diagram of the procedure for rectal and vaginal swabbing, and a large poster with the same instructions was placed in the washroom where the women self-sampled. If they preferred, women could also self-sample in the examination room. Physicians, nurse practitioners, and midwives performed the test during the clinic visit according to their usual practice. Clinicians may not have been blinded to test sequence.

Sample Size and Measures

The primary study hypothesis was that the two sampling methods would detect an equal number of infections. We defined equivalence as a difference of 10% or less in the prevalence of GBS as determined by self-testing and physician testing methods. Assuming a local prevalence of infection of 23% (personal communication, Dr Fiona Smail, Director of Medical Microbiology, Department of Laboratory Medicine, McMaster University), a maximum

Flow of recruitment and follow-up of participants

difference between the tests of 10%, a type 1 error rate of 5% (2-tailed), and a power ($1-\beta$) of 80%, we calculated a need for 330 subjects to rule out any difference in prevalence greater than 10%.

Participating women completed a questionnaire on demographics and preference for self-testing versus clinician testing at the start of the visit. We asked women who refused participation to provide limited demographic information and to indicate their reasons for refusal from a list (do not want to do self-sampling, do not want to have physician sampling, do not want to do research, do not have time, feel physically unable to self-sample, and do not want to have two tests done). Women were also asked to indicate their perceived preference before testing. The preference question was a 7-point Likert scale ranging from “strongly prefer self” to “strongly prefer clinician.” After completing all testing, women answered another questionnaire about the acceptability of self-sampling and clinician testing (Likert scale, ranging from “totally acceptable” to “not at all acceptable”) and answered the preference question again. The study was approved by the research ethics board of Hamilton Health Sciences.

Laboratory Methods

Swabs were collected in charcoal transport media and incubated in Todd-Hewitt GBS-selective broth (containing gentamicin and nalidixic acid) for 18 to 24 hours and were then subcultured to a CNA plate and incubated for 18 to 24 hours in CO_2 at 35°. Beta-hemolytic colonies resembling GBS were confirmed using a catalase test and latex grouping. This testing was conducted in the Department of Laboratory Medicine at St. Joseph’s Healthcare.

Statistical Methods

We compared the proportion of women who tested positive for GBS using each method through a normal approximation to the binomial distribution. We calculated the sensitivity of each method for detecting infection, using the presence of a positive result by either method as the reference standard. We used McNemar’s chi-square test to estimate agreement between the two methods. Ratings of perceived preference and socioeconomic characteristics were compared between women who refused and women who agreed to participate in self-sampling, using chi-square, Fisher exact, or t tests as appropriate. Data were analyzed using SPSS version 13.0 (SPSS Inc., Chicago, IL).

Table 1. Characteristics of women who participated and refused self-sampling for GBS

	Participants (n = 330) % (n)	Refusers (n = 31*) % (n)	χ^2 value	P
Age < 20	8.3 (27/327)	19.4 (6/31)		0.05†
Never married	13.8 (45/327)	32.3 (10/31)		0.02†
High school incomplete	6.7 (22/326)	16.1 (5/31)		0.07†
Primigravid	58.6 (192/326)	53.3 (16/30)	0.35	0.55
Prefer physician sampling	21.2 (69/326)	54.8 (17/31)	17.6	.001
Speak a language other than English at home	23.1 (66/286)	23.1 (66/286)	1.37	0.24

* 31/56 refusers completed the questionnaire.

†Fisher exact test used due to expected cell count <5, all others are Pearson's chi-square.

RESULTS

Of the 386 women we approached, 330 (85.5%) agreed to participate (Figure). Of the 56 who refused, 31 completed the questions on characteristics, reason for refusal, and preference for clinician or self-sampling. The most common reasons for refusal included being averse to self-sampling (38.7%; 12/31), wanting only one test to be done (22.6%; 7/31), and feeling physically unable to do the test (16.1%; 5/31). Of the 22 women who also refused to complete the questionnaire, the most common reason for refusal given to the clinic receptionist was being uncomfortable with self-sampling (68.2%; 15/22). The characteristics of women who participated and refused are shown in Table 1. The average age of the women who participated was 27.2 years (standard deviation 5.42), and 58.9% (192/326) were primiparous.

Women who refused participation were significantly more likely to prefer clinician sampling than women who participated (54.8% vs. 21.2%; Pearson's chi square = 17.6_{df=1}, $P < 0.001$) and were more likely to have never been married (32.3% vs. 13.8%; continuity-corrected chi square = 6.1_{df=1}, $P = 0.02$). In a logistic regression model, with age, education, marital status, parity, preference for sampling method, and speaking a language other than English at home entered into the model, having less than high school education (odds ratio [OR] 3.96; 95% confidence intervals [CI] 1.17–13.41, $P = 0.03$) and having a preference for clinician sampling (OR 6.86; 95% CI 2.76–17.08, $P < 0.001$) were significant predictors of refusal.

One hundred sixty-seven women were randomized to perform self-sampling first, and 163 to have clinician sampling first. The prevalence of GBS infection was 18.8% (62/330) in clinician-obtained samples and 17.0% (56/330) in self-obtained samples. The Pearson's correlation between tests was 0.90 ($P < 0.001$). The difference in prevalence was 1.8% (95% CI 2.0–6.0). There were 64 infections detected

by either method; eight were detected by clinician sampling only and two by self-sampling only (McNemar's chi-square_{df=1} = 3.6, $P = 0.11$). Sensitivity was 87.5% (95% CI 77.0–93.8) for self-obtained specimens and 96.9% (95% CI 88.7–99.8) for clinician-obtained specimens.

Among participating women at baseline, 27.3% preferred self-sampling, 56.3% had no preference, and 22.7% preferred clinician sampling. The majority (63.8%) did not change their preference after sampling, and most of the women who changed their preference (91.8%; 101/110) changed from self or clinician to no preference. A small number of women changed their preference from clinician to self (1.8%; 2/110) or self to clinician (6.3%; 7/110). Eighty-nine percent (274/307) of participants rated the acceptability of clinician collection as totally or somewhat acceptable, and 81.5% (251/308) rated the acceptability of self-collection as totally or somewhat acceptable.

DISCUSSION

The results of this study show that self-sampling for GBS is as effective as clinician sampling at 35 to 37 weeks' gestation. This finding is consistent with the findings of four previous studies.^{7–10} Self-sampling was an acceptable alternative for the majority of our participants and was preferable for approximately one quarter of these women. Women who were never married were more likely to prefer clinician sampling. After both tests, less than 7% of women changed their preference for the mode of sampling. In the three previous studies that reported patient preference, two found that 58% of women preferred self-sampling,^{7,10} and in the third study, 75% of women were neutral or preferred self-sampling (preference for self-sampling alone was not reported).⁸ The lower preference for self-sampling reported in the present study may be due to our heterogeneous patient population. On average, our patient population is younger than those of most previous studies^{8–10} and is more socioeconomically and ethnically diverse. Characteristics of

Table 2. Patient characteristics and preference for sampling method in the two randomized groups of pregnant women

	Self-sampling first (n = 167) % (n)	Clinician sampling first (n = 163) % (n)
Age < 20	9.7 (16/165)	6.8 (11/162)
Never married	16.4 (27/165)	11.1 (18/162)
High school incomplete	7.3 (12/164)	6.2 (10/162)
Primiparous	61.2 (101/165)	56.5 (91/161)
Speak a language other than English at home	20.5 (30/146)	25.7 (36/140)
Prefer physician sampling	16.5 (27/164)	26.0 (42/162)

the patient population are shown in Table 2. It is possible that women who are younger and of lower socioeconomic status are less comfortable with self-care than the women of higher socioeconomic status who participated in the study reported by Molnar et al.⁸ and that women from non-North American cultures find self-sampling less acceptable.

The benefits of self-sampling include increased autonomy for women, increased patient involvement in obstetrical care, and increased office efficiency. Self-sampling can easily be done in the bathroom while collecting a urine sample and could also be done at home just prior to the office visit. There were a number of open-ended comments that suggested women enjoyed the autonomy afforded by the offer and the ability to perform self-sampling.

Our study is the first to randomize the test sequence correctly and to test women at the recommended sampling time of 35 to 37 weeks' gestation. Studies that alternated sampling sequence based on systematic non-random methods and studies that did not alternate sampling sequence at all may overestimate the detection rate for the first collection method by obtaining a more adequate sample. Although we found the prevalence of GBS from both sampling methods was slightly lower than expected from the local laboratory data, our CI for the difference between test prevalence ruled out a difference of greater than 2% in favour of self-sampling or of greater than 6% in favour of clinician sampling.

In addition, we measured preferences in all women, both before and after testing, and recorded the reasons for refusal among women who declined to participate. Refusal to participate may have been related to characteristics or experiences in addition to education, such as prior experience with Pap smears or tampon use. Approximately one half of the reasons for refusal were unrelated to an aversion to self-sampling. For example, some women did not want to have more than one swab done at the visit. These women

may have been comfortable with self-sampling if it had been offered as a single alternative. We did not specifically ask women if they were concerned about collecting their own sample incorrectly, but 14.2% (47/330) who self-sampled commented on the questionnaire that they were concerned about not doing the test correctly. In other studies describing women who prefer clinician sampling, women were concerned that they did not perform the test correctly.⁸ Clinicians may reduce patients' anxiety about their ability to perform self-sampling by informing them about the accuracy of the self-sample.

At the MCH, a non-physician staff member explained self-sampling to the women with the help of written instructions and an explanatory diagram produced by a graphic artist. These measures effectively facilitated self-sampling among women. Study recruitment was not a strain on clinical staff time. These results may be less applicable to lower volume settings such as solo family practices with less staff support. However, many women noted anecdotally that the diagram and the instructions were very helpful, and these tools may reduce instruction time needed to teach women the correct self-sampling techniques. For widespread use of self-sampling for GBS in other settings, similar resources would be required. In addition, multiple translations may help remove language barriers to self-sampling. However, the study assistant was a staff member of the clinic and it is possible that some women over-stated the acceptability of self-sampling and some women who refused may not have felt comfortable admitting aversion to self-sampling as the reason for refusal.

CONCLUSION

On the basis of evidence of accuracy and patient preference, this study supports the option of offering self-sampling for GBS at 35 to 37 weeks' gestation to all pregnant women, even in heterogeneous patient populations with ethnically diverse and very young unmarried

women. The majority of women will likely prefer self-sampling or will have no strong preference for either method. Our study suggests that only a small proportion of women will prefer clinician sampling, which should also be available.

ACKNOWLEDGEMENTS

This study was funded by Hamilton Health Sciences Research Development Fund and Physician Services Inc. Foundation. The findings were presented in part at the North American Primary Care Research Group Annual Meeting October 15–18, 2005, Quebec City, Quebec, and Trillium Primary Care Research Forum, Toronto, Ontario, June 10, 2005.

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