



history of prematurity when bacterial vaginosis is treated with oral metronidazole. However, while 94 patients were initially randomized to metronidazole or placebo, 14 patients were lost to follow-up, failed to finish their assigned treatment or required treatment with other antibiotics. Thus, the analysis was based on 80 patients. Others have cautioned that in cases where there has been loss of patients to follow-up, a check of the validity of the findings can be done by assuming that all patients in the intervention group not accounted for did universally poorly and those unaccounted for in the control group all did well.³ If the conclusions are unchanged, then one can have more confidence in the findings. It is interesting that in the published discussion following the study, one of the discussants recommends that this be done.²

The table below includes the data from the original paper and a re-analysis subject to the above 'test.' Had all 94 patients been accounted for, and assuming an equal randomization, there would have been 47 in the treatment group (44 reported on) and 47 in the control group (36 reported on). The re-analysis assumes that the three unaccounted for women in the metronidazole group had the events that were to be averted. In the control group, the 11 unaccounted for women are assumed not to have had these events.

When the study is re-analysed accounting for losses to follow-up, the most important outcomes of preterm delivery and low birth weight are no longer significant. Thus, the study's conclusions fail this test of robustness. This raises concerns about the validity of the recommended clinical practice guideline. Such a guideline is likely to be influential in determining clinical practice,

given the SOGC's credibility with practising physicians. Although we are all committed to reducing the incidence of preterm birth, we would suggest that the current evidence is not strong enough to support the position taken by the SOGC at this time, and that a re-evaluation of the guideline recommendation may be warranted.

Yours sincerely,
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ON BEHALF OF THE SOGC COMMITTEE ON BACTERIAL VAGINOSIS, DR. BOUCHARD REPLIES.

TO THE EDITOR:

We read with great interest comments from the group at Mt. Sinai Family Medicine Centre in Toronto, about the SOGC guidelines on Bacterial Vaginosis (BV), and are very pleased that our recommendations are being scrutinized so thoroughly.

The Toronto group questions the recommendation of the SOGC Committee based on Morales' study about screening for BV in high-risk pregnant women. They suggest that the results of that study did not meet one essential characteristic that guarantees the study to be acceptable for quality in controlled trials. Based on the recommendation of Guyatt *et al.*¹ in, "Users Guide to the Medical Literature," they reject without appeal the conclusions from Morales' study. After their own re-analysis, assuming an hypothetical worst case scenario for the fourteen missing patients, they obtained new results which are not statistically significant. The committee does not believe that, on the basis of re-analysis using Guyatt's recommendation, the Guideline should be changed. We wish to explain why.

Outcome	Original Report			Re-analysis		
	Rx (n=44)	Control (n=36)	p	Rx (n=47)	Control (n=47)	p
Hospital admission for preterm labour >1	12	28	<0.05	15	28	<0.05
GA at delivery <34 weeks	-	10	<0.05	3	10	0.07*
<37 wks	2	4	NS	5	4	NS
BW <2,500 gms	8	16	<0.05	11	16	0.25
PROM	6	12	<0.05	9	12	0.46
	2	12	<0.05	5	12	0.06

*Fisher's exact test.



The SOGC clinical practice guidelines on BV were written in 1996 by the Clinical Practice-Gynaecology Committee and endorsed by the Clinical Practice-Obstetrics, and Social and Sexual Issues Committees. The 1996 Clinical Guidelines on BV were written as an update on BV in non-pregnant and pregnant women. The Committee did not include all specific references on BV and pregnancy that were reviewed to support our opinions and we apologize for that. Based on the results from Morales' study, the Committee recommended screening for BV in asymptomatic patients with a history of preterm births and treatment to reduce the risk of subsequent preterm births, but more studies were reviewed to support this recommendation. Not all of these studies were cited.

In 1995, Hauth *et al.*² concluded that treatment with metronidazole and erythromycin reduced rates of premature delivery in women with BV and an increased risk for preterm delivery. In 1995, Hillier *et al.*³ demonstrated that BV was associated with preterm delivery of low-birth-weight infants independently of other recognized risk factors. Results from a 1995 prospective controlled evaluation by McGregor *et al.*⁴ showed that BV was associated with increased risks of pregnancy loss for preterm premature rupture of membranes and preterm birth. Orally administered clindamycin was associated with a 50 percent reduction in BV-linked preterm birth and preterm rupture of membranes.

The American College of Obstetricians and Gynecologists (ACOG) recently published a Committee Opinion⁵ on bacterial vaginosis screening for prevention of preterm delivery, and noted the following strategy for screening and treatment of BV after the first trimester: "Screening for BV may be considered in women at high risk for preterm labor." Moreover, in January 1998, the Center for Disease Control and Prevention (CDC) issued the New Guidelines for Treatment of Sexually Transmitted Disease⁶ and stated "Because treatment of BV in high-risk pregnant women (i.e. those who have previously delivered a premature infant) who are asymptomatic might reduce preterm delivery, such women may be screened and those with BV can be treated."

Many questions remain to be addressed, especially about the benefit of screening and treatment in low-risk asymptomatic pregnant women in the hope of reducing the prematurity and cost related to this event.

Based on evidence from the literature and recent recommendations from ACOG and CDC, the SOGC Committee maintains the position given in its published guidelines and recommends screening and treatment of BV in high-risk pregnant women.

Yours sincerely,
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On behalf of the SOGC Committee on
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