The Effect of Transvaginal Ultrasound, Vaginal Examination, or Coitus on Fetal Fibronectin Results: A Systematic Review

Abstract #416

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Background

- The manufacturers of fetal fibronectin (fFN) discourage its use in the setting of recent transvaginal ultrasound (TVU), sterile vaginal examination (SVE), and coitus due to concern for false positive results.
- The objective of this study was to conduct a systematic review to determine if cervical manipulation or coitus affects the accuracy of fFN results.

Materials and Methods

- An electronic search of 7 online databases using a combination of pertinent keywords was performed.
- The primary outcome was the agreement between pre- and post-intervention fFN swabs.
- Secondary outcomes included frequency in which the fFN result changed after cervical manipulation and percentage of discordant pairs.
- Statistical analysis
  - Overall proportion agreement and kappa statistics calculated for TVU and SVE studies.
  - Cumulative RR estimated for coitus studies.

Results

807 studies identified through the search algorithm → 6 included in the final analysis, with one study assessing the effect of more than one intervention:

- TVU: 3 studies (n=346 specimen pairs)
  - 93.4% agreement between specimen pairs before and after TVU with kappa 0.69 (CI, 0.57-0.81)
- SVE: 2 studies (n=122 specimen pairs)
  - 88.5% agreement between specimen pairs before and after SVE with kappa 0.69 (CI, 0.54-0.84)
- Coitus: 2 studies (n=262 specimen pairs)
  - RR 5.6 (95% CI, 3.0-10.6)

Cervical manipulation via transvaginal ultrasound or sterile vaginal examination does not significantly affect fetal fibronectin results; therefore its use after these exposures is clinically acceptable.

Conversely, fFN use in the setting of recent coitus should continue to be discouraged.

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Table 1: Outcomes for Transvaginal Ultrasound

Outcomes	Study			Composite Results
	Ben-Haroush, 2010	Golic, 2017	Turitz, 2016	
fFN result changed from negative to positive[a]	0/25 (0)	1/77 (1.3)	12/203 (5.9)	**13/305 (4.3)**
fFN result changed from positive to negative[b]	0/3 (0)	4/19 (21.1)	6/19 (31.6)	**10/41 (24.4)**
Total discordant pairs[c]	0/28 (0)	5/96 (5.2)	18/222 (3.2)	**23/346 (6.6)**
Proportion agreement [d]	100% [κ 1.0 (1.0-1.0)]	94.8% [κ 0.83 (0.68-0.97)]	91.9% [κ 0.55 (0.36-0.73)]	**93.4% [κ 0.69 (0.57-0.81)]**

Abbreviations: fFN, fetal fibronectin.
Data are n/N (%) unless otherwise specified.
[a] N = total negative first fFN results, [b] N = total positive first fFN results, [c] N = total number of fFN sample pairs, [d] Data presented as percentage [kappa (95% confidence interval)].

Table 2: Outcomes for Sterile Vaginal Exam

Outcomes	Study		Composite Results
	McKenna, 1999	Turitz, 2016	
fFN result changed from negative to positive[a]	5/34 (14.7)	2/58 (3.4)	**7/92 (7.6)**
fFN result changed from positive to negative[b]	2/16 (12.5)	5/14 (35.7)	**7/30 (23.3)**
Total discordant pairs[c]	7/50 (14.0)	7/72 (9.7)	**14/122 (11.5)**
Proportion agreement [d]	86.0% [κ 0.69 (0.59-0.90)]	90.3% [κ 0.66 (0.43-0.89)]	**88.5% [κ 0.69 (0.54-0.84)]**

Abbreviations: fFN, fetal fibronectin
Data are n/N (%) unless otherwise specified.
[a] N = total negative first fFN results, [b] N = total positive first fFN results, [c] N = total number of fFN sample pairs, [d] Data presented as percentage [kappa (95% confidence interval)].

Table 3: Outcomes for Coitus

Outcomes	Study		Composite Results	
	Faron, 2015	McLaren, 2015	Total	RR (95% CI)
Positive fFN results	15/60 (25) vs. 6/80 (7.5)	33/61 (54.1) vs. 4/61 (6.6)	**48/121 (39.7) vs. 10/141 (7.1)**	**5.6 (3.0-10.6)**
Concentration of fFN, ng/mL	68.3 (37.0-99.6) vs. 20.2 (5.7-34.8)[a]	53 (6-189) vs. 5 (2-12)[b]	--	--

Abbreviations: fFN, fetal fibronectin; CI, confidence interval; RR, relative risk.
Data are n/N (%) in exposure group vs. n/N (%) in control group.
[a] Data presented as mean (95% CI) in exposure group vs. mean (95% CI) in control group, [b] Data presented as median (interquartile range) in exposure group vs. median (interquartile range) in control group.