A Parallel-Group, Randomized Trial Examining Impact of Colposcopy Results Delivery by a Nurse Liaison on Patient-Reported Outcomes and Adherence

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ABSTRACT

Objectives: Cervical cancer is on the rise in Canada. Addressing patient anxiety and improving patient understanding of colposcopy and results may improve adherence. This randomized controlled trial examined the impact of colposcopy results delivery by a Nurse Liaison versus the referring primary care provider (PCP) on patient anxiety, and secondary outcomes including patient satisfaction, knowledge of diagnosis, and 9-month adherence to follow-up.

Methods: Patients ≥18 years old presenting for initial appointment at the study colposcopy clinic were randomized 1:1 to an intervention group (Nurse Liaison) versus a control group (PCP). After receiving colposcopy results, participants completed online measures of anxiety (State-Trait Anxiety Inventory), health care satisfaction scales (Patient Satisfaction Questionnaire-18, Health Anxiety Inventory, Visit-Specific Satisfaction Questionnaire-9), self-reported colposcopy diagnosis, and demographics. Chart review at 9 months assessed adherence to recommended colposcopy follow-up. Groups were compared on continuous and categorical variables, controlling for diagnosis severity and trait anxiety.

Results: The intervention group had significantly lower state anxiety with State-Trait Anxiety Inventory-state mean scores of 37.3 versus 40.7 in controls ($P = 0.03$). Intervention group participants were more likely to correctly report their diagnosis (84% vs. 66.3%, $P = 0.003$). Questionnaire responders were more likely to be in the intervention group and had a higher proportion of cervical intraepithelial neoplasia 2+ pathology. There were no differences in demographics, patient satisfaction, or adherence to follow-up between groups.

Conclusions: Direct delivery of colposcopy results by a trained Nurse Liaison was associated with decreased patient anxiety around colposcopy results, and increased patient knowledge regarding diagnosis. This model may be considered to improve patient-centred care.

Keywords: colposcopy; cervical cancer; cervical intraepithelial neoplasia; patient-reported outcomes; patient education; psychosocial oncology

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RÉSUMÉ

Objectif : Le cancer du col de l'utérus est en augmentation au Canada. Il est possible d'améliorer l'observance des patientes en se préoccupant de leur anxiété et en leur expliquant bien la colposcopie et les résultats. Cet essai clinique randomisé a examiné l'impact de la transmission des résultats de colposcopie par une infirmière de liaison ou par le médecin de première ligne (MPL) demandeur sur l'anxiété des patientes. Les critères de jugement secondaires étaient la satisfaction des patientes, la connaissance du diagnostic et l'observance du suivi à 9 mois.

Méthodes : Les patientes de 18 ans ou plus se présentant pour un premier rendez-vous à la clinique de colposcopie de l'étude ont été assignées aléatoirement, dans un ratio de 1:1, dans le groupe intervention (infirmière de liaison) ou le groupe témoin (MPL). Après avoir reçu les résultats de la colposcopie, les participantes ont rempli en ligne l'échelle d'anxiété (STAI) et les échelles de satisfaction des soins de santé (PSQ-18, HAI, VSQ-9) et donné leur diagnostic autodéclaré de la colposcopie et leurs caractéristiques démographiques. L'examen des dossiers à 9 mois a permis d'évaluer l'observance du suivi post-colposcopie recommandé. Les groupes ont été comparés en fonction de variables continues et nominales en prenant en compte la gravité du diagnostic et le trait d'anxiété.

Résultats : Le groupe intervention présentait un état anxiété significativement plus faible, le score moyen de l'échelle STAI étant de 37,3 comparativement à 40,7 dans le groupe témoin ($P = 0,03$). Les participantes du groupe intervention étaient plus susceptibles de correctement déclarer leur diagnostic (84 % p/r à 66,3 %; $P = 0,003$). Les personnes ayant répondu au questionnaire étaient plus susceptibles d'appartenir au groupe intervention et avaient une plus forte proportion de pathologies CIN2+. Il n'y a pas eu de différences entre les groupes en ce qui concerne les caractéristiques démographiques, la satisfaction des patientes et l'observance du suivi.

Conclusion : La communication directe des résultats de la colposcopie par une infirmière de liaison qualifiée a été associée à une diminution de l'anxiété des patientes face aux résultats de l'examen et à une augmentation des connaissances des patientes concernant le diagnostic. Ce modèle peut être envisagé pour améliorer les soins centrés sur la patiente.

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INTRODUCTION

Cervical cancer is now the most rapidly increasing cancer in Canadian women, despite being largely preventable.[1] In line with the World Health Organization's 2020 global strategy to eliminate cervical cancer, the Canadian Partnership Against Cancer's action plan calls for improved uptake of primary human papillomavirus vaccination, human papillomavirus primary screening, and follow-up of abnormal screening including timely and effective colposcopy.[2] A systematic review of nonadherence to colposcopy found default rates of 3% for first appointments and 11%–12% for subsequent visits.[3] Default from colposcopy increases the risk of missed or delayed diagnosis of cervical precancers or cancers,[4] reduces health system efficiency, and increases costs.[5]

Anxiety is the most prominent psychological factor impacting the patient colposcopy experience; up to 60% of colposcopy patients exceeded the State-Trait Anxiety Inventory (STAI) threshold in 1 study.[6] Anxiety may stem from fears of having cancer, a lack of understanding of colposcopy, and uncertainty regarding next steps,[7] and is a risk factor for increased pain and discomfort during colposcopic procedures, as well as nonadherence to colposcopy.[3,7,8] Delays in the communication of colposcopy results to patients or primary care providers (PCPs), and a lack of patient understanding, can worsen anxiety and nonadherence,[8–10] but this can be addressed with patient navigators providing appointment reminders, simplified education regarding tests, and rationale, and follow-up for abnormal results with counselling.[8,11,12]

Routine practice in the study multiprovider colposcopy clinic was for colposcopy results and recommendations to be delivered to patients primarily by the referring PCP, with colposcopists contacting patients directly for unexpected or high-risk findings, or management recommendations outside the standard colposcopy algorithm. In preparation for this randomized trial, we asked focus groups of colposcopy patients to describe their experiences with the current colposcopy reporting system. These results informed the development of the Nurse Liaison intervention in this trial.

We hypothesized that delivery of colposcopy results by a trained Nurse Liaison, embedded in the colposcopy clinic, would improve patient psychological and satisfaction outcomes, as well as adherence to colposcopy recommendations.

METHODS

Participants

Patients presenting for their initial colposcopy appointment were recruited from the waiting room by the Nurse Liaison from July 2017 to May 2018. Eligible patients were ≥18 years old and able to communicate in English. Exclusion criteria included: inability or refusal to provide informed consent, pregnant patients (due to different algorithm for colposcopy in pregnancy), previous colposcopy experience, and no PCP available to provide results and continuity of care.

Measures

This was a single-institution, parallel-group randomized trial. The primary outcome was patient anxiety regarding receipt of colposcopy results, measured by the self-reported state subscale of the STAI[13]—one of the most widely-used measures of cross-sectional anxiety in response to a situation or environment,[13] and previously validated in patients with abnormal cervical cytology.[14] Secondary outcomes included patient satisfaction (Short Form Patient Satisfaction Questionnaire [PSQ]-18,[15] Health Anxiety Inventory [HAI],[16] and Visit-Specific Patient Satisfaction Questionnaire [VSQ]-9[17]), accuracy of self-reported colposcopy diagnosis, and 9-month adherence to colposcopy follow-up.

The full trial protocol was registered and is available on ClinicalTrials.gov (NCT03296566). This study was approved by the Clinical Research Ethics Board (H16-03194), and the manuscript was prepared in line with CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting randomized trials.[18]

Procedure

Consenting participants received a study identification number and were randomized 1:1 in blocks of 4 to receive their results from the Nurse Liaison (intervention group) versus their PCP (controls) using a REDCap randomisation algorithm. The Nurse Liaison provided colposcopy education to all participants prior to their appointment. Group allocation was revealed to participants at the completion of the colposcopy visit for safety so that they knew who to contact for results if not contacted by a health care provider. Colposcopists were blinded to the allocation group until after the completion of the colposcopy visit.

Following the colposcopy appointment, patient charts were labelled with their group allocation, to facilitate identification by the colposcopists for results reporting according to the designated study group.

Upon return of pathology results, the colposcopists prepared their colposcopy reports to be sent to the PCP within 2–3 weeks, with customization regarding the delivery of results to the patient according to group allocation. In both arms, if there were findings concerning for invasive cancer or a need for expedited management outside the standard colposcopy algorithm, patients were contacted directly by the colposcopists.

In the intervention group, the Nurse Liaison delivered final colposcopy results and recommendations, provided education about their significance, and assisted with appointment booking. In addition to colposcopy pamphlets and website links, she was supported by the reporting colposcopists for patient questions or concerns beyond her scope. Telephone contact attempts and interactions were documented in the patient's chart.

Study questionnaire data were collected and managed using REDCap. Four weeks after their colposcopy visit (to allow time for them to have received results), participants were emailed the link to online questionnaires containing the following items: STAI Form Y (with the 20-item STAI-S and 20-item STAI-Trait subscale measuring underlying disposition towards anxiety)[13,19]; health care satisfaction scales (PSQ-18,[15] HAI,[16] VSQ-9[17]); self-reported colposcopy diagnosis; and demographics. Reminder emails were sent at 5 and 6 weeks after the initial visit, and a research assistant telephoned a final reminder at 7 weeks. Those who did not complete the questionnaire after 3 reminders were considered lost to follow-up.

A research assistant, blinded to the allocation group, reviewed patient charts after at least 9 months following the initial visit for cytologic, histologic, and appointment adherence data. This interval allowed for minor delays in the context of a maximum 6-month recall interval after the first appointments.

Statistical Analysis

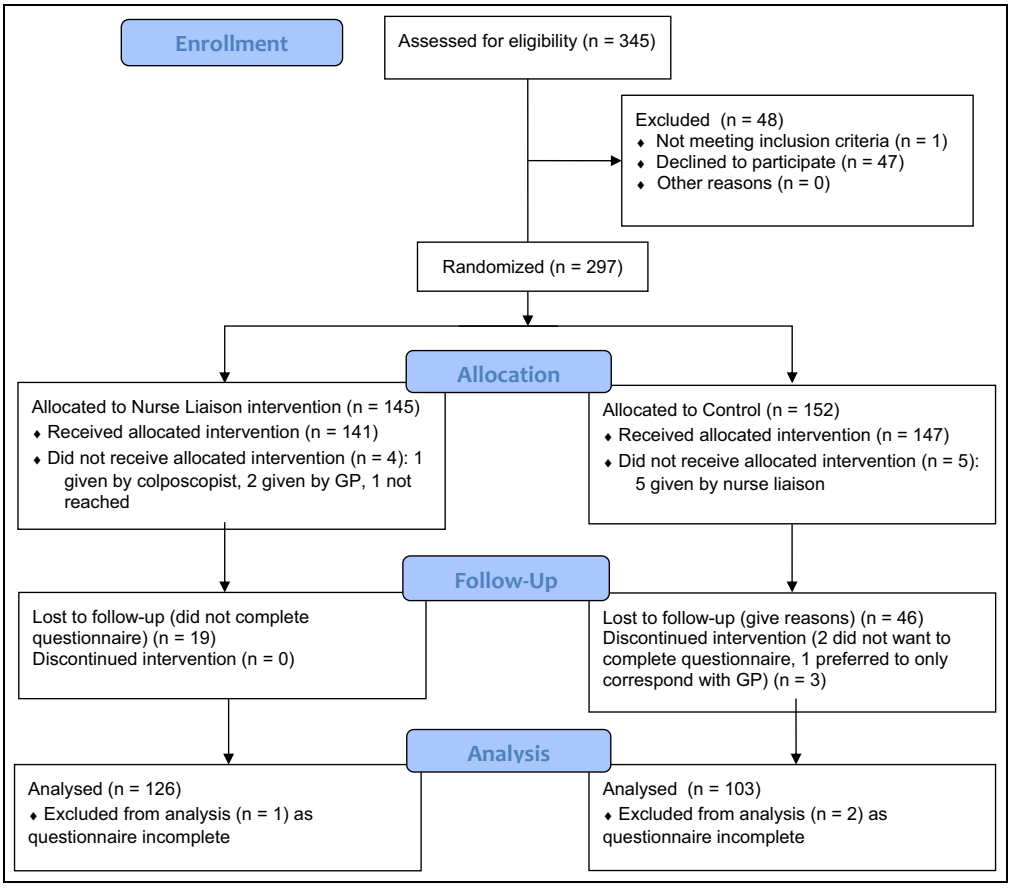
Overall, 85 participants with completed surveys per group were required to detect a difference of 5.3 in mean STAI-S scores between the groups—half of an SD is considered clinically significant[19,20]—with 90% power and 2-tailed alpha of 0.05. Accounting for a 15% loss to follow-up, we aimed to recruit 100 participants per group. Demographic and clinical variables were compared between the groups using Wilcoxon rank sum tests for continuous data and Fisher exact tests for categorical data. The primary outcome (STAI-S) was compared using a *t* test. Secondary outcomes were compared between the groups using *t* tests for continuous variables and Fisher exact tests for categorical variables. A multiple linear regression model was built to examine the difference between the groups in STAI-S scores while controlling for STAI-T scores, and the severity of colposcopic pathology results.

RESULTS

The Nurse Liaison approached 345 new colposcopy patients between July 2017 to May 2018; 1 did not meet the inclusion criteria (pregnant) and 47 declined to participate. An interim analysis was performed 8 months into recruitment upon reaching the randomization target of 100 per group (111 controls and 113 to the intervention group). As loss to follow-up was greater than anticipated in both arms (22% in the intervention and 45% in the control group), to reach the required sample size of 85 completed questionnaires per group, the recruitment goal was increased to 150 per group.

The flow diagram of study participants is shown in Figure. At the completion of recruitment, 297 participants were randomized (145 to the intervention group and 152 controls). Post-randomization and after receiving their results, 3 participants from the control group withdrew. Four

Figure. CONSORT 2010 flow diagram for study participants.



CONSORT: Consolidated Standards of Reporting Trials.

intervention group participants did not receive their results from the Nurse Liaison: 1 was contacted directly by the colposcopist to expedite a diagnostic excisional procedure, 2 received results from their PCP before being contacted by the Nurse Liaison, and 1 could not be reached despite multiple attempts (a letter was sent to their PCP). Eight control participants did not receive results per protocol. Three with a cancer diagnosis received results directly from the colposcopists. Five received results from the Nurse Liaison: 4 of these had not received their results from their PCP despite multiple contact attempts, and thus were given results for safety, and 1 was contacted in error. Loss to follow-up with failure to complete the questionnaire occurred in 19 intervention group participants and 46 control participants, and 3 participants (1 control, 2 intervention) only completed part of the questionnaire. Nine-month chart review was completed for all participants regardless of questionnaire completion. Intention-to-treat analysis of questionnaire-based outcomes was thus completed for 125 intervention and 101 control participants.

Demographic and clinical variables are summarized in Table 1. There were no differences between the groups except that intervention group participants were significantly more likely to have completed the questionnaire. Among those who completed versus did not complete the questionnaire, there were no significant differences in age, education or employment. Questionnaire responders were more likely to have high-grade (cervical intraepithelial neoplasia 2-3) pathology ($P = 0.001$); 49 of the 52 participants with cervical intraepithelial neoplasia 3 (94%) were in the responder group. There was no difference between groups in the mean number of days between colposcopy and questionnaire completion (40.1 days in controls vs. 38.4 days for the intervention group, $P = 0.38$).

Table 1. Baseline characteristics of the participants

Characteristics	Total (N = 294)	Control (n = 149)	Intervention (n = 145)	*P* value[a]
Completed the questionnaire				
Yes	229 (77.9)	103 (69.1)	126 (86.9)	0.0002
No	65 (22.1)	46 (30.9)	19 (13.1)	
Age (y)				
Median (IQR)	33.0 (27.0–44.0)	31.0 (27.0–44.0)	33.0 (28.0–43.5)	0.64
Missing	63 (21.4)	45 (30.2)	18 (12.4)	
Education				
High school to some undergraduate	72 (24.5)	34 (22.8)	38 (26.2)	0.87
Undergraduate or postgraduate degree	105 (35.7)	47 (31.5)	58 (40.0)	
Postdoctoral training-other	54 (18.4)	23 (15.4)	31 (21.4)	
missing	63 (21.4)	45 (30.2)	18 (12.4)	
Employment				
Full time	149 (50.7)	71 (47.7)	78 (53.8)	0.072
Part-time	26 (8.8)	9 (6.0)	17 (11.7)	
Self-employed	25 (8.5)	15 (10.1)	10 (6.9)	
Unemployed, retired, homemaker, student	31 (10.5)	9 (6.0)	22 (15.2)	
Missing	63 (21.4)	45 (30.2)	18 (12.4)	
Ethnicity				
Eurocaucasian	136 (46.3)	58 (38.9)	78 (53.8)	0.11
East Asian	38 (12.9)	16 (10.7)	22 (15.2)	
Other	43 (14.6)	26 (17.4)	17 (11.7)	
Missing	77 (26.2)	49 (32.9)	28 (19.3)	
Pathology diagnosis				
Negative	105 (35.7)	54 (36.2)	51 (35.2)	0.45
CIN 1	75 (25.5)	41 (27.5)	34 (23.4)	
CIN 2	59 (20.1)	25 (16.8)	34 (23.4)	
CIN 3	52 (17.7)	26 (17.4)	26 (17.9)	
Adenocarcinoma of cervix	1 (0.3)	1 (0.7)	0 (0.0)	
Adenocarcinoma of endometrium	1 (0.3)	1 (0.7)	0 (0.0)	
Serous ovarian carcinoma	1 (0.3)	1 (0.7)	0 (0.0)	

All values are n (%) unless otherwise specified.

[a]*P* values are from Wilcoxon rank sum tests for continuous variables and Fisher exact tests for categorical variables. *P* value less than 0.05 denotes significance.

For the primary outcome of patient anxiety after receiving colposcopy results (Table 2), significant anxiety (STAI-S score $\geq$40[21,22]) was experienced by 51.5% of controls and 37.6% of intervention participants. Mean STAI-S scores were lower in intervention participants (37.3 [12.8] vs. 40.7 [11.2], $P = 0.037$, Cohen's d = 0.28). This remained significant after controlling for the severity of the diagnosis, and underlying predisposition to anxiety measured by STAI-T scores ($P = 0.032$).

Secondary outcomes are shown in Table 2. Intervention group participants were significantly more likely to correctly self-report their colposcopy diagnosis (84% vs. 66% of controls, $P = 0.003$). There were no differences in STAI-T score, HAI, PSQ-18, VSQ-9, or adherence to follow-up between groups. Approximately 30% of participants per group were discharged to their PCP following their initial colposcopy appointment for cytologic surveillance. Of the remainder who were recommended to follow-up in colposcopy, adherence was 91.1% in the intervention arm and 96.9% in controls ($P = 0.19$).

DISCUSSION

This randomized controlled trial in a culturally diverse and high-volume colposcopy centre found that compared to results delivery by the PCP, delivery of colposcopy results with education and supportive counselling by a Nurse Liaison significantly decreased patient anxiety even after controlling for severity of histology and baseline anxiety

Table 2. Primary and secondary outcomes by randomisation group

Outcomes	Total (N = 226)	Control (n = 101)	Intervention (n = 125)	*P* value[a]	Effect size[b]
STAI-State score					
Mean (SD)	38.8 (12.2)	40.7 (11.2)	37.3 (12.8)	0.04	0.28
Proportion with STAI-State score ≥40, n (%)	99 (43.8)	52 (51.5)	47 (37.6)	0.04	0.14
STAI-Trait score					
Mean (SD)	38.9 (11.0)	39.8 (10.4)	38.3 (11.4)	0.31	0.14
HAI score					
Mean (SD)	15.2 (7.2)	15.4 (6.2)	15.1 (7.9)	0.77	0.04
PSQ-18 score					
Mean (SD)	65.4 (11.3)	65.1 (11.1)	65.6 (11.4)	0.79	0.04
VSQ-9 score					
Mean (SD)	67.5 (18.8)	66.6 (18.2)	68.3 (19.2)	0.49	0.09
Diagnosis perceived correctly, n (%)					
Yes	172 (76.1)	67 (66.3)	105 (84.0)	0.003	0.21
No	54 (23.9)	34 (33.7)	20 (16.0)		
Adherence to colposcopy follow-up, n (%)					
Discharged to GP (no colposcopy follow-up)	70 (31.0)	35 (34.7)	35 (28.0)	0.19	0.12
Attended colposcopy follow-up	146 (64.6)	63 (63.4)	82 (65.6)		
Did not attend colposcopy follow-up	10 (4.4)	2 (2.0)	8 (6.4)		

[a]*P* values are from *t* tests for continuous variables and Fisher exact tests for categorical variables. *P* value less than 0.05 denotes significance.

[b]Cohen's d for continuous variables and Cramer's V for categorical variables.

GP: general practitioner; HAI: Health Anxiety Inventory; PSQ: Short Form Patient Satisfaction Questionnaire; STAI: State-Trait Anxiety Inventory; VSQ: Visit-Specific Patient Satisfaction Questionnaire.

and improved the accuracy of self-reported colposcopy diagnosis.

While anxiety has been identified as a risk factor for nonadherence with colposcopy, a systematic review did not find conclusive evidence that interventions to reduce anxiety result in improved adherence,[3] in line with our study findings. However, other studies have found a strong association between lack of knowledge about colposcopy and nonadherence[23]; Lerman et al.[8] found that this was the most significant factor related to default in 50% of respondents, followed by psychological barriers in 35%.[8] One prospective study found that an educational brochure to prepare patients for colposcopy significantly decreased anxiety and increased knowledge regarding colposcopy, suggesting a relationship between enhanced patient education and psychological outcomes.[24] However, Onyeka and Martin-Hirsch reported that nearly 25% of women who had received written information about colposcopy still sought more complete verbal counselling over the phone with an experienced provider and that only 50% knew their recommended follow-up, which may have negatively impacted adherence.[25] The Nurse Liaison intervention addresses these types of gaps by providing continuity of care, from pre-colposcopy education to results reporting, with education, counselling and guidance for subsequent follow-up.

Limitations to this study include that participants were non-blinded, although it was deemed necessary for patient safety for them to know who to contact for results if they were not received in a timely manner. The importance of this was demonstrated by all 5 participants in the control group who received their results off-protocol from the Nurse Liaison because they were unable to access their PCP—another benefit of the Nurse Liaison approach. There was a significantly higher survey response rate in the intervention arm, which could have biased the results. However, this may signal a greater degree of patient engagement with care because of the continuity offered by the Nurse Liaison intervention. This study was not powered to detect a difference in adherence between groups; it was high in both arms which may have been influenced by participation bias. Finally, this single-institution study may not be generalizable to other settings.

In conclusion, receiving colposcopy results and counselling from a trained Nurse Liaison may decrease anxiety and improve patient knowledge of their diagnosis. Both may be

correlated to adherence,[3,7,8,23] and are also important factors in colposcopy quality of care. A 2023 Canadian survey suggests that 22% of Canadians and 19% of Canadians who identify as women do not have a PCP.[26] A centralised and patient-centred mode of colposcopy education and results delivery may be especially important for this vulnerable group. Redistributing the task of routine results delivery from physicians to trained, expert nurses may also reduce health care system costs. With the overarching aim of improving patient-centredness in care and eliminating cervical cancer, an important future direction would be to investigate the impact of centralized models of colposcopy results delivery, such as this Nurse Liaison intervention, on patient-reported outcomes, adherence, and cost-effectiveness in a larger cohort.

ETHICS

University of British Columbia Clinical Research Ethics Board H16-03194.

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