What Proportion of Canadian Women Will Accept an Intrauterine Contraceptive at the Time of Second Trimester Abortion? Baseline Data From a Randomized Controlled Trial

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Abstract

Objective: This report details enrolment findings related to a Canadian randomized controlled trial comparing immediate to delayed intrauterine contraception (IUC) placement after a second trimester abortion. We report acceptance of IUC, satisfaction with prior contraception, adherence to the CONSORT criteria, and challenges faced in the recruitment process.

Methods: Women seeking second trimester abortion and selecting either of two methods of IUC as their preferred contraception method were enrolled and randomized to insertion either immediately post-abortion or four weeks later. Enrolled participants completed a Contraception Satisfaction Questionnaire detailing prior contraceptive satisfaction.

Results: Among 1813 women assessed, 1500 (83%) met eligibility criteria and IUC was chosen for post-abortion contraception by over one half of them (792/1500, 53%). When both types of device were available cost-free, women selected the levonorgestrel-releasing intrauterine system more than 20 times more frequently than a copper IUD. Participants had an average age of 26.0 (standard deviation [SD] 6.8) years, and an average gestational age of 16.1 (SD 3.1) weeks. Almost one half (48.4%) had had a prior abortion and 46.9% had a prior delivery. Two thirds of participants were using a contraception method at the time of conception, but almost one third of these were using methods in the lowest tiers of effectiveness. There was a weak correlation between prior contraceptive compliance and education level.

Conclusion: More than one half of eligible women seeking a second-trimester abortion chose IUC for post-abortion contraception. In Canada, health care for unintended pregnancies is universally subsidized but contraception is not. Offering comprehensive information on the range of contraceptive methods and providing cost-free IUC is an effective strategy to increase uptake of intrauterine contraception among Canadian women who wish to prevent further unintended pregnancy.

Key Words: Abortion, induced, Canada, family planning, health services, sexual health

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Résumé

Objectif : Ce rapport présente, de façon détaillée, les résultats en matière de participation issus d'un essai comparatif randomisé canadien ayant comparé la mise en place immédiate d'un dispositif de contraception intra-utérine (CIU), à la suite d'un avortement mené au deuxième trimestre, au report d'une telle mise en place. Nous nous y prononçons au sujet de l'acceptation de la CIU, de la satisfaction envers le mode de contraception utilisé au préalable, du respect des critères CONSORT et des défis rencontrés dans le cadre du processus de recrutement.

Méthodes : Nous avons sollicité la participation de femmes demandant à obtenir un avortement au deuxième trimestre

et choisissant l'un de deux modes de CIU à titre de mode de contraception privilégié; ces femmes ont par la suite été affectées au hasard à un groupe devant bénéficier de l'insertion du mode de CIU choisi immédiatement à la suite de l'avortement ou à un groupe devant bénéficier d'une telle insertion quatre semaines plus tard. Les participantes ont rempli un questionnaire au sujet de la satisfaction en matière de contraception qui cherchait à rendre compte de leur satisfaction envers les modes de contraception utilisés au préalable.

Résultats : Parmi les 1 813 femmes évaluées, 1 500 (83 %) ont satisfait aux critères d'admission et plus de la moitié d'entre elles (792/1 500, 53 %) ont choisi la CIU à titre de mode de contraception post-avortement. Lorsque les deux types de dispositifs étaient offerts gratuitement, les femmes ont choisi le système intra-utérin à libération de lévonorgestrel plus de 20 fois plus fréquemment que le DIU de cuivre. L'âge moyen des participantes était de 26,0 ans (écart-type [σ] : 6,8 ans) et leur âge gestationnel moyen était de 16,1 semaines (σ : 3,1 semaines). Près de la moitié des participantes (48,4 %) avait déjà connu un avortement et 46,9 % d'entre elles avaient déjà connu un accouchement. Les deux tiers des participantes utilisaient un mode de contraception au moment de la conception; toutefois, près du tiers d'entre elles utilisaient des modes de contraception se situant aux niveaux d'efficacité les plus faibles. Une faible corrélation a été constatée entre l'observance du mode de contraception utilisé au préalable et le niveau de scolarité.

Conclusion : Plus de la moitié des femmes admissibles demandant à obtenir un avortement au deuxième trimestre ont choisi la CIU à titre de mode de contraception post-avortement. Au Canada, les soins de santé offerts en présence d'une grossesse non souhaitée sont universellement couverts par l'État, mais la contraception ne l'est pas. L'offre de renseignements exhaustifs au sujet de la gamme des modes de contraception disponibles et le fait d'offrir un accès gratuit à la CIU constituent une stratégie efficace, en vue d'accroître la mesure dans laquelle une contraception intra-utérine est réclamée par les Canadiennes qui souhaitent prévenir d'autres grossesses non souhaitées.

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INTRODUCTION

Abortion is common in Canada, with nearly one third of all women having had at least one abortion.[1] Canadian women seeking abortion represent a high-risk group for recurrent unintended pregnancy, because 37% have had at least one prior abortion.[2] About 12% of all abortions occur past the 12th week of pregnancy (i.e., in the second trimester).[2–4]

Intrauterine contraception is one of the most effective forms of contraception.[5–8] Current IUC product monographs advise delaying insertion after a second trimester abortion until uterine involution at four to six weeks post-abortion.[9,10] Recent evidence suggests an overall benefit of immediate insertion.[11–15]

We have previously reported our protocol for a randomized controlled trial comparing immediate versus delayed insertion of IUC after second trimester abortion.[16] Using government health administrative data and clinical charts to examine clinical and cost outcomes at one to five years post-enrolment, this trial will provide comprehensive information on health system costs and insertion timing effectiveness for IUC among women having a second trimester abortion. Access to administrative data will provide the unique ability to report on one-year pregnancy rates with a near perfect set of outcome data.

We describe here the recruitment challenges, demographic characteristics, and prior contraceptive satisfaction among women enrolled in this RCT. Additionally, we examine the acceptance of methods of IUC among women seeking second trimester abortion after cost and knowledge barriers are addressed.

ABBREVIATIONS

CSQ	contraception satisfaction questionnaires
DMPA	depot medroxyprogesterone acetate
IUC	intrauterine contraception
LNG-IUS	levonorgestrel-releasing intrauterine system
SD	standard deviation

METHODS

All women presenting for a second trimester abortion at any British Columbia abortion clinic were screened for eligibility (Table 1). Detailed methods are described in our protocol[16] and are briefly summarized here. Women planning to use IUC for post-abortion contraception chose either a copper IUD (Flexi-T380+, Prosan International BV, Arnhem, The Netherlands) or a levonorgestrel-releasing intrauterine system (Mirena, Bayer Inc., Toronto ON), and were then offered participation in an information session to learn about the study. Potential participants were aware during their contraception counselling session that IUC methods were available without cost through the study. Consenting participants were randomly allocated to an insertion time immediately or four weeks after their abortion.[16] Medical costs related to abortion care, IUC insertion, and ultrasound are insured within the government health plan for all residents of British Columbia. The study sites offered free or low cost one-month packages of combined hormonal contraception, or one injection of DMPA. Otherwise, subsidized contraception is not available to most women in this population.

Contraception satisfaction questionnaires and demographic characteristics were collected at the time of enrolment. All analyses were carried out using the statistical software R (R Foundation for Statistical Computing, Vienna, Austria). Proportions were compared using Pearson's chi-squared

Table 1. Eligibility criteria

Inclusion criteria

- Have completed informed consent for an abortion over 12 and under 24 weeks' gestational age.
- Have chosen IUC (either LNG-IUS or copper IUD) for contraception post-abortion.
- Are residents of British Columbia registered with the provincial Medical Services Plan.

Exclusion criteria

- Intention to move from British Columbia within the next year
- Intention to conceive within the next year.
- Any of the following contraindications to use of a LNG-IUS or a copper IUD:
  - Uterine cavity anomalies causing distortion of the endometrial canal including fibroids of more than 5 cm, excluding repaired uterine septum
  - Current untreated PID (recent infection is not a contraindication to IUC insertion)
  - Wilson's disease (if choosing a copper IUD)
  - Undiagnosed abnormal uterine bleeding
  - Known uterine or cervical malignancy or cervical dysplasia
  - Known or suspected progestin-dependent neoplasia, including breast cancer (if choosing a LNG-IUS)
  - Active liver disease or dysfunction (if choosing a LNG-IUS)
  - Actual benign or malignant liver tumours (if choosing a LNG-IUS)
  - Hypersensitivity to levonorgestrel or any of the other ingredients in the formulation or component of the container components of Mirena (if choosing a LNG-IUS)
  - Bacterial endocarditis
  - Established immunodeficiency (HIV positivity is not an exclusion unless immunodeficient)
  - Acute malignancies affecting blood or leukemias
  - Recent trophoblastic disease while hCG levels are elevated
  - Currently enrolled in another investigational study
- Post-randomization exclusion
  - Failure to undergo an abortion
  - Uterine perforation at the time of abortion
  - Bleeding of more than 500 mL during abortion
  - Uterine cavity anomalies detected at the time of abortion

test with Yates continuity or Fisher exact test. Student *t* test and analysis of variance were used to compare means of continuous variables. Spearman's coefficient was used to report correlations. Statistical significance was declared when $P < 0.05$.

We undertook a questionnaire pilot study described elsewhere[16] to adapt the CSQ from an existing validated questionnaire.[17] The CSQ questions evaluate participants' prior contraceptive satisfaction on eight scales, each yielding a score out of a maximum of 100: ease of use/convenience; efficacy; symptoms and side effects; menstrual impact; lifestyle impact; compliance; confidence; and overall satisfaction. Higher scores indicate increased satisfaction. The CSQ development, validation, and translation pilot was completed at the time recruitment began for the main study, and thus study participants enrolled in the pilot study phase (a pre-study implementation to determine feasibility) provided basic demographics and indicated prior contraceptive method use but did not complete the CSQ. As pilot study participation was offered solely to women who chose to use a copper IUD, many of the CSQ questions are missing among the copper IUD cohort. With this exception, the pilot study utilized identical protocols and procedures.

Institutional review board approval was received from the University of British Columbia Children's and Women's Hospital Research Ethics Board, and the trial was registered at Controlled Trials.

RESULTS

Enrolment for this study took place from April 28, 2010, to September 30, 2011, at all clinics providing second trimester abortion in British Columbia. In addition, 62 women were recruited during a copper-device-only RCT pilot study (16 June 2009 to 27 April 2010) and are included in the final

CONSORT figure indicating recruitment and allocation for the randomized controlled trial: immediate vs. delayed insertion of intrauterine contraception after second trimester abortion

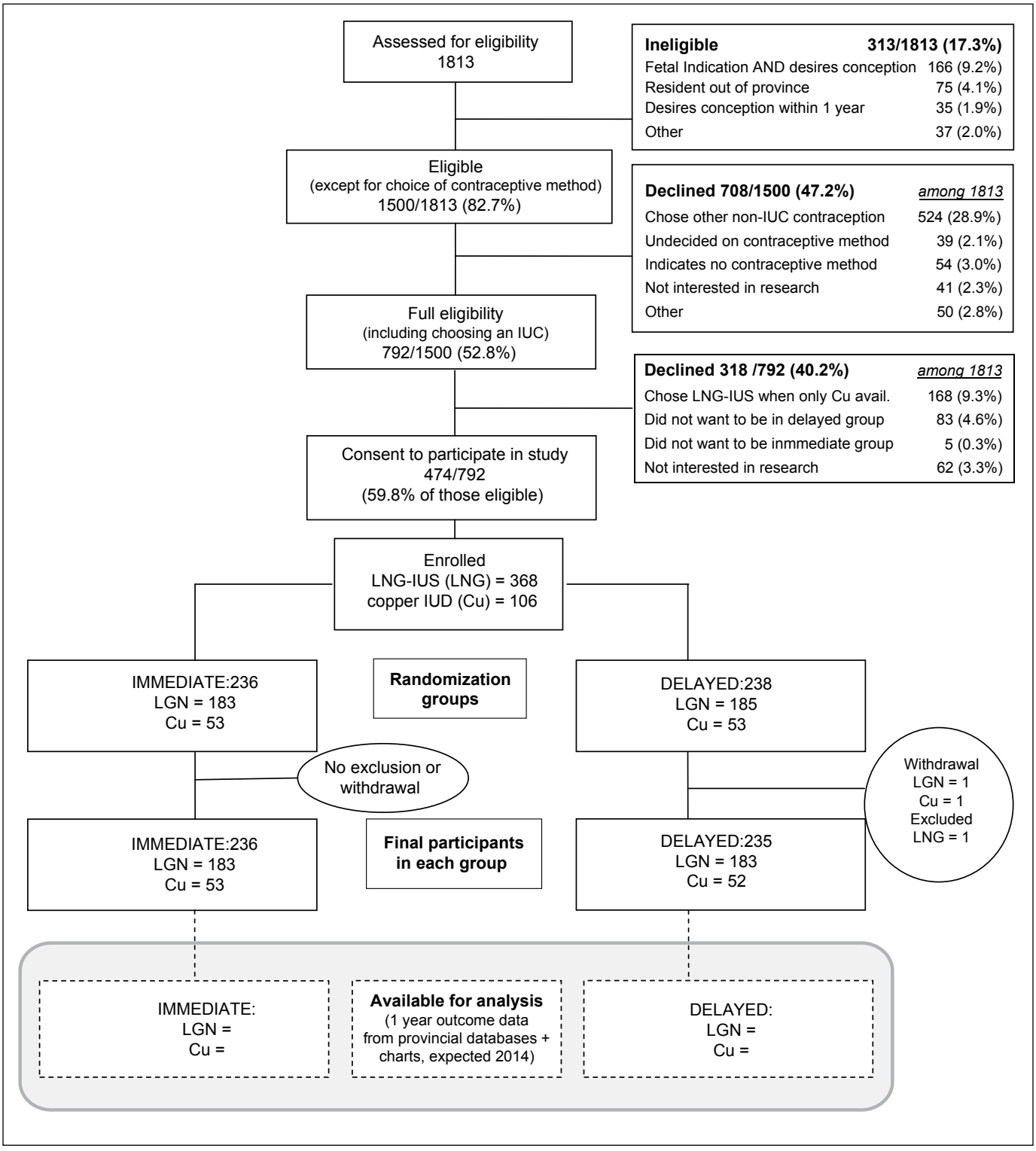

Table 2. Participant baseline characteristics

	LNG-IUS				Copper IUD			
	Immediate		Delayed		Immediate		Delayed	
n	183		183		53		52	
Average age (SD)	25.6 (6.7)		26.1 (7.1)		26.9 (6.6)		25.8 (5.6)	
Average gestational age, weeks (SD)	16.1 (3.1)		15.9 (3.1)		16.4 (3.0)		16.7 (3.2)	
	n	%	n	%	n	%	n	%
Any prior delivery	89	48.7	91	49.5	25	48.1	16	30.8
Any prior abortion	81	44.3	92	50.0	26	50.0	29	55.8
Chlamydia positive	11	6.0	6	3.3	2	3.8	2	3.8
Education completed								
< High school	46	25.1	52	28.4	9	17.0	7	13.5
High school	66	36.1	57	31.1	18	34.0	16	30.8
> High school	71	38.8	74	40.4	26	49.1	29	55.8
Currently enrolled in an education program	48	26.2	47	25.5	8	15.4	4	7.7
Current enrolment not reported	3	1.6	2	1.1	28	53.8	31	59.6
Annual income, $								
0 to 14 999	98	53.5	103	56.0	12	22.6	7	13.5
15 000 to 24 999	37	20.2	34	18.5	5	9.4	5	9.6
25 000 to 54 999	33	20.1	40	21.7	7	13.2	8	15.3
> 55 000	10	5.5	2	1.1	0	0	0	0
Not reported	5	2.7	4	2.7	29	54.7	32	61.5

cohort. Among 1813 women presenting to study clinics for second trimester abortions during this 27-month period, 313 were not eligible, including 201 (11.1%) who wished to conceive again within a year. The majority of these 201 women had sought an abortion for fetal indications. Additionally, 75 (4.1%) were either not residents of British Columbia registered with the provincial health services plan, or planned to move out of British Columbia within a year, and would not be able to participate in follow up through the health administrative databases (Figure). Of 1500 residents of British Columbia who did not wish to conceive within the year following the abortion, more than one half (52.8%) chose to use IUC following their abortion. Among these, the majority (60%, 494/792) agreed to participate in the study. Approximately one in five (21.2%, 168/792) chose not to participate because they wished to use LNG-IUS during the pilot phase when this was unavailable in the study, and another 11% (88/792) did so to avoid randomization, as they preferred to ensure immediate insertion. Thus we enrolled 474 women into this RCT. One woman was excluded after randomization because she was found to have a bicornuate uterus. Two women from the delayed insertion group withdrew from the study immediately after randomization. Thus 471 women currently will be eligible for future analysis: 366 in the LNG-IUS groups and 105 in the copper IUD groups. We plan to conduct the first analysis of related post-enrolment health administrative data in 2014, allowing capture of all data related to pregnancies conceived, contraception dispensed, and complications arising within the first year after enrolment; this will be followed by four subsequent annual analyses.

During study periods in which both IUC devices were available, women demonstrated an overwhelming preference for the LNG-IUS over the copper IUD, selecting it with a ratio of 368:18. The demographic variables in the four enrolment groups are shown in Table 2. Women chose their preferred IUC and then were randomized to immediate or delayed insertion, with no differences in characteristics between the randomized groups at baseline.

Overall the average age of women entering the study was 26.0 (SD 6.8) years, and was similar between devices chosen and between randomized groups for each device. Participants overall had an average gestational age of 16.1 weeks (SD 3.1 weeks) at the time of the abortion procedure. Almost one half (48.4%) had a prior abortion, with 46.9% having at least one prior delivery.

Of the women who participated, 24.2% had not completed high school but almost one half (42.5%) had completed post-secondary training of some type. Comparing demographic variables and CSQ experiences scales between

Table 3. Most recent contraceptive methods used by participants

	Method N = 471	Most effective method n (%)	Contraceptive users %	Women using more than one method n (%)
Tier 1	Implant* IUC† Female sterilization Vasectomy	8 (1.7)	2.5	2 (25.0)
Tier 2	DMPA‡ Lactational amenorrhea Hormonal contraception: oral, patch, vaginal ring§	189 (40.1)	60.0	66 (33.2)
Tier 3	Condoms Diaphragm Cervical shield Fertility awareness Emergency contraception	93 (19.7)	29.5	89 (57.4)
Tier 4	Withdrawal Spermicide alone	3 (0.6)	0.9	41 (93.2)
Type not reported		22 (4.7)	7.0	
None		156 (33.1)		

*Implants are not currently available in Canada but include long-acting progesterone releasing implantable devices obtained by participants from outside Canada.

†Intrauterine contraception including copper-releasing or levonorgestrel-releasing devices.

‡Depot medroxyprogesterone acetate

§Combined hormonal contraception releasing devices such as the contraceptive patch and the contraceptive vaginal ring.

the self-selected groups of participants by type of IUC chosen (i.e., not a randomized variable) yielded only one parameter with a significant ($P < 0.05$) difference: "highest education achieved." Participants choosing LNG-IUS were less likely to have completed high school (26.8% vs. 15.2%). A majority of enrolled women (63.9%) reported an annual income of less than $25 000. When those currently enrolled in an educational or training program were excluded, still more than one half of enrolled women (57.5%) had income below $25 000 annually. Almost all (97.9%) identified English as one of their spoken languages, followed by Punjabi (1.7%), and Tagalog (1.1%).

The method of contraception used at the time of conception of the current pregnancy is shown in Table 3, listed in the tiers of contraception described by the World Health Organization.[18] One third (33.1%) of all women were not using any method of contraception. Of the women using a contraceptive method, almost one third (30.5%) were using one from the two lowest tiers (withdrawal, spermicide, fertility awareness, and barrier methods) as their most effective contraceptive method. Moderately effective methods (DMPA, lactational amenorrhea, and combined hormonal contraceptives) were used by 60.0% of women who reported using at least one method. Highly effective methods, such as any form of IUC, had been in use at conception for only eight women (2.5% of those using contraception and 1.7% of all participants). Implants were very rarely used, and have not been available in Canada since 2002.[19] Only 27 women (5.7%) reported that their contraceptive method was paid for by a health benefits plan.

CSQ scores at the time of recruitment are shown in Table 4. Overall, participants reported moderate satisfaction with the side effect profile of the contraception they had been using at the time the current pregnancy was conceived, with a score of 77.7 on the 100 point scale; they did not report a major impact on lifestyle (score 73.9). The lowest scores were noted in satisfaction with the impact of their contraception related to menstrual factors (41.0), compliance factors (43.6), and assurance/confidence in their contraceptive method (50.6). Overall satisfaction scores were also relatively low at 48, although there was a trend towards increased satisfaction with tier 1 methods (Table 4). The compliance score was positively associated with increasing education level, with a Spearman's coefficient of 0.19. No difference on any CSQ scale was apparent between women choosing the LNG-IUS or the copper IUD.

DISCUSSION

In this study we have demonstrated a high rate of acceptance of IUC among women seeking second trimester abortion.

Table 4. Scaled measurement of prior contraception satisfaction related to tier of effectiveness of most effective method used at time of conception

CSQ Domain*	Overall† n = 256 mean (SD)	Tier 1 n = 8 mean (SD)	Tier 2 n = 171 mean (SD)	Tier 3 n = 74 mean (SD)	Tier 4 n = 3 mean (SD)
Ease of use	62.4 (20.3)	87.1 (10.2)	61.6 (18.4)	62.1 (22.2)	69.4 (16.9)
Efficacy	62.2 (28.6)	90.6 (18.6)	61.8 (27.8)	62.1 (29.1)	41.7 (14.4)
Side effect bother	77.7 (16.0)	83.0 (5.2)	74.9 (15.3)	83.2 (17.0)	80.3 (17.5)
Menstrual impact	41.0 (24.3)	43.5 (16.8)	45.9 (24.1)	30.2 (22.4)	26.4 (12.2)
Lifestyle impact	73.9 (19.3)	76.4 (17.2)	72.5 (19.5)	77.3 (19.4)	60.7 (6.2)
Compliance	43.6 (24.5)	80.5 (18.7)	40.6 (24.5)	47.4 (20.8)	43.7 (16.5)
Assurance/confidence	50.6 (19.6)	57.1 (25.4)	51.3 (19.2)	48.9 (19.6)	48.1 (22.0)
Overall satisfaction	48.0 (22.3)	65.1 (24.1)	48.7 (22.1)	44.2 (22.2)	47.2 (18.8)

All participants in the LNG-IUC groups completed the CSQ upon entry into the study but not all of the participants in the CuT380A groups, as many were enrolled during the pilot study prior to the availability of the CSQ.

*Scale scores range from 0 to 100, where a higher score indicates greater satisfaction

†Each domain is calculated as an average score on multiple questions related to that domain. In order to calculate a domain score, the participant must have answered 50% or more of the relevant questions. As some women did not complete all questions in the CSQ, the n varies across domains in the overall score, as well as within the tiers.

The rate of IUC use at the time of conception was only 1.7% in our population, less than half the rate previously reported among reproductive age women in Canada.[20] The low rate of use of IUC among those seeking abortion (i.e., our study population) likely reflects the increased effectiveness of IUC over other methods. IUC users are less likely to be faced with an unintended pregnancy than women using other contraceptives, and so are less likely to request abortion.

We found that over one half of eligible women chose a form of IUC post abortion, a rate that is higher than previously reported in similar populations in which IUC was not provided without cost.[11,13,14] As an internal comparison this is also higher than the proportion choosing to use an LNG-IUS (21.2%) during a phase of the study when only the copper IUD was available cost-free. The marked acceptance of IUC in our population, compared with documented Canadian use estimated at less than 5%,[20] is likely partially due to the current renewed interest in IUC, especially LNG-IUS, as an option for contraception, a trend that has been documented in the United States.[21] Access to highly knowledgeable counsellors with current information on risks and benefits of all contraception options was likely also a contributing factor.

Women seeking abortion are often highly motivated to prevent a subsequent pregnancy; thus, the time of abortion may represent a window of acceptability for a highly effective health intervention such as provision of IUC. It is possible that a lack of money, a lack of accurate knowledge about IUC, or both, are barriers to uptake. Other studies[22] have also found an increase in the uptake of long-acting contraception when it is provided cost-free, which suggests that the upfront cost of these methods poses a significant barrier for some women, despite cost-effectiveness over the long term.[23,24]

We encountered difficulty in recruiting women to the copper IUD groups. Women in our study considering use of IUC demonstrated a more than 20-fold preference for the LNG-IUS. Similarly, during the two study phases when we offered only a copper IUD cost-free, women eligible for the study frequently preferred to arrange independently for placement of an LNG-IUS. CSQ scores indicated that women entering the trial were dissatisfied with the effect of their previous contraceptive method on their menstrual cycle. Thus, the possibility of side effects associated with use of the copper IUD, such as heavier menstrual flow and increased dysmenorrhea, may have deterred women from choosing this method.

Our recruitment has shown that many women preferred having IUC insertion immediately after abortion. Over one quarter of eligible women who declined enrolment did so to ensure immediate insertion, despite having to procure their IUC personally. Two women randomized to the delayed insertion group immediately withdrew, citing a preference for immediate insertion. This highlighted an area for improvement in our informed consent process, which we addressed through enhanced recruiter training and monitoring.

It is unclear why women choosing the LNG-IUS were less likely to have completed high school. Even when women less than 19 years old are excluded, still 19.6% of women choosing the LNG-IUS had not completed high school, compared with 7.4% of the women choosing the copper IUD. It may be that the preference to use a non-hormonal method is concentrated among women with relatively more education. This question deserves further study.

Our cohort was socioeconomically disadvantaged; nearly two thirds of participants reported an annual income of less than $25 000, more than the 52.7% of Canadian reproductive age women reporting an income in this range in the 2006 Canadian Census.[25] Only one in 20 women reported having insurance coverage for prescription drugs that could help cover the cost of contraception, and only 13.4% of participants reported having any form of extended health benefits (beyond the basic health care provided for all Canadians), well below the national average of 60% to 80%.[26,27]

WHO tier 1 or 2 (highly effective or very effective) contraceptive methods were used by 41.8% of participants at the time they conceived the current pregnancy. However, CSQ compliance scores were low (mean score 43.6), indicating that the participants may have had difficulty adhering to their method. Few studies using this scoring system have been reported, but in the initial validation study reported by Colwell et al.[17] the average compliance score was 77.3. Mathias et al. administered the questionnaire to 56 women who were dissatisfied with their birth control method and planning to change methods, and found an average compliance score of 57.[28]

We found that over one half of participants reported either not using any method of contraception at the time of conception or using a method in the lowest two tiers of effectiveness. Participants did not report concerns about side effects or lifestyle impact of their prior contraceptive method, with CSQ scores similar to those reported in previous studies.[20] The average menstrual impact score in this study (41) was similar to that reported by Mathias et al.[28] for women dissatisfied with their method of contraception (47). The low confidence scores were not unexpected in this population, given that all participants had experienced a contraceptive failure. The overall mean satisfaction score (50.6) was much lower than that reported by Colwell et al. (81.3).[17]

The major limitation of this study is the lower than expected enrolment for the copper IUD groups, due largely to the very strong preference eligible participants expressed for the LNG-IUS. The accuracy of the questionnaire could have been affected by patient recall bias, although subjects were asked to recall impressions from only a few months in the past.

CONCLUSION

We found a high acceptance of immediate post-abortion intrauterine contraception among women seeking second trimester abortion. Women desiring IUC were over 20 times more likely to choose the LNG-IUS than a copper IUD when cost was not a consideration. In our cohort, women choosing the copper IUD had a higher overall level of education than those who chose the LNG-IUS. Compliance and effect on menstrual function were identified as specific areas of dissatisfaction with previous contraceptive methods. The LNG-IUS is well suited for this population because it combines the highest contraceptive effectiveness with a minimal need for compliance and a beneficial effect on menstrual function. Our study conditions included offering comprehensive accurate information on the range of contraceptive methods, and insertion of the IUC device without cost to participants.

Canadian health jurisdictions currently provide universal insurance coverage for management of unintended pregnancies, but not for contraception. Provision of IUC by the health care system at the time of abortion is highly acceptable to women and could be an effective strategy to improve women's health.

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