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**Early provision of intrauterine
contraception after first trimester
induced abortion – complications,
adherence to post-abortion care,
recovery and risk of subsequent abortion
during the first year**

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Doctoral dissertation

To be presented for public discussion with the permission of the Faculty of Medicine of the University of Helsinki, in the Seth Wichmann Auditorium of the Department of Obstetrics and Gynecology, Helsinki University hospital, on the 12th of April, 2019 at noon.

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Contents

Abbreviations.....	5
1 List of original publications.....	6
2 Abstract.....	7
3 Introduction.....	9
3.1 Terminology.....	11
4 Review of the literature	13
4.1 Induced abortion globally and in Finland.....	13
4.1.1 Finnish legislation and policies	16
4.1.2 Medical and surgical abortion.....	18
4.2 Return of ovarian function and fertility after abortion.....	19
4.3 Contraceptive methods; efficacy, adherence continuation.....	20
4.3.1 in primary prevention	20
4.3.2 In secondary prevention	22
4.4 Initiation of contraception after termination of pregnancy.....	23
4.5 Barriers in post-abortion care.....	24
4.6 Recovery after abortion	25
4.6.1 Mental well-being.....	27
4.6.2 Sexual well-being.....	27
5 Aims of the study	28
6 Subjects and methods	29
6.1 Study design.....	29
6.1.1 Interventions and follow-up.....	31
6.1.2 Questionnaires	32
6.2 Study on the success of early IUD insertion after medical termination of pregnancy (I)	33
6.3 Study on non-compliance (II)	34
6.4 Study on subsequent termination of pregnancy (III)	34
6.5 Study on mental health and quality of life (IV).....	35
6.6 Study on sexual well-being (V).....	35
6.7 Study approvals and registrations.....	35

6.8	Statistical analysis	35
7	Results	37
7.1	Study on the success of early insertion after MTOP (I).....	37
7.2	Study on non-compliance (II)	39
7.3	Study on the need of subsequent TOP (III)	40
7.4	Study on mental health (IV).....	42
7.5	Study on sexual well-being (V).....	43
8	Discussion	46
8.1	Contraceptive choice and the risk of subsequent termination of pregnancy	46
8.2	Safety and timing of IUD insertion after termination of pregnancy.....	46
8.3	Verifying the outcome of medical termination of pregnancy.....	47
8.4	Compliance to post-abortion care.....	48
8.5	Contraceptive services after termination of pregnancy	49
8.6	Recovery after termination of pregnancy.....	51
8.7	Strengths and weaknesses of the study.....	52
8.7.1	Study I	53
8.7.2	Study II.....	53
8.7.3	Study III	53
8.7.4	Study IV and V.....	54
9	Conclusions	55
10	Acknowledgements.....	56
11	References	58
12	Summary in Finnish.....	73
12.1	Tausta	73
12.2	Tutkimusasetelma	73
12.3	Tulokset	74
13	Original publications	75

Abbreviations

BMI = Body mass index

Cu-IUD = Copper intrauterine device

EQoL = Euro-Quality of Life questionnaire

hCG = Human chorionic gonadotropin

HR = Hazard ratio

IQR = Interquartile range

ITT = Intention-to-treat analysis

IUD = Intrauterine device

LARC = Long-acting reversible contraception

LNG-IUS = Levonorgestrel-releasing intrauterine system

MFSQ = McCoy Female Sexuality Questionnaire

MTOP = Medical termination of pregnancy

OC = Oral contraceptives

PHC = Primary health care

PP = Per protocol analysis

QoL = Quality of life

STAI = State-trait anxiety inventory

TOP = Termination of pregnancy

VAS = Visual analogue scale

1 List of original publications

- I Pohjoranta E, Mentula M, Suhonen S, Heikinheimo O. Intrauterine contraception after medical abortion: factors affecting success of early insertion. *Contraception* 2017;95(3):257-262.
- II Pohjoranta E, Mentula M, Suhonen S, Heikinheimo O. Predicting poor compliance with follow-up and intrauterine contraception services after medical termination of pregnancy. *BMJ Sex Reprod Health* 2018; 44:278-285.
- III Pohjoranta E*, Mentula M*, Gissler M, Suhonen S, Heikinheimo O. Provision of intrauterine contraception in association with first trimester induced abortion reduces the need of repeat abortion: first-year results of a randomized controlled trial. *Human Reproduction* 2015; 30(11): 2539-2546.

Pohjoranta E, Mentula M, Gissler M, Suhonen S, Heikinheimo O. Corrigendum. Provision of intrauterine contraception in association with first trimester induced abortion reduces the need of repeat abortion: first-year results of a randomized controlled trial. *Human Reproduction* 2019; 34(3): 587-588.
- IV Toffol E*, Pohjoranta E*, Suhonen S, Hurskainen R, Partonen T, Mentula M, Heikinheimo O. Anxiety and quality of life after first-trimester termination of pregnancy: a prospective study. *Acta Obstetrica et Gynecologica Scandinavica* 2016; 95(10): 1171-80.
- V Pohjoranta E, Mentula M, Hurskainen R, Suhonen S, Heikinheimo O. Sexual well-being after first trimester termination of pregnancy: secondary analysis of a randomised contraceptive trial. *Acta Obstetrica et Gynecologica Scandinavica* 2018; 97(12): 1447-1454.

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2 Abstract

In Finland more than every third abortion is performed to a woman with history of previous abortion, which indicates suboptimal contraceptive use and inadequacy of postabortion contraceptive services. Previous studies have shown that long-acting reversible contraceptive (LARC) methods, especially intrauterine devices (IUD) are most efficient in preventing repeat unwanted pregnancy. IUDs can usually be inserted at the time of surgical termination of pregnancy (TOP). After medical TOP (MTOP), an IUD can be inserted when the abortion is shown to be complete, commonly 1–4 weeks afterwards, according to various recommendations. However, attendance at post-abortion contraceptive visits is poor, and thus the planned IUD insertion often fails.

We have conducted a randomized trial assessing early postabortal IUD insertion provided comprehensively as a part of abortion services. Altogether 748 women undergoing a first trimester TOP were recruited and randomized into two groups. Women in the intervention group received an IUD (either a LNG-IUS or a Cu-IUD, according to the woman's choice), at the hospital providing the TOP, either at the time of surgical TOP or at a follow-up visit 1–4 weeks after MTOP. Women in the control group were prescribed oral contraceptives and advised to contact their primary health care (PHC) unit for IUD insertion, according to the current practice and the national guideline. All study participants were provided with a questionnaire assessing anxiety, quality of life (QoL) and sexual well-being at baseline, as well as three months and one year after the TOP.

The primary outcome was to assess the effects of the intervention on the incidence of subsequent TOP, when compared to the normal practice. In this thesis, the results of the first year are described. In addition, incidence of complications related to early IUD insertion, as well as compliance to post-abortion care and IUD insertion were assessed in women choosing MTOP. As secondary outcomes, mental health and sexual well-being during the first year after TOP was assessed.

During the first year of follow-up after TOP, a significant difference between the two study groups was seen in the attendance at follow-up, in receiving the planned IUD, and in the incidence of repeat unwanted pregnancy. The early insertion of IUD after MTOP was safe and did not increase the risk of severe complications or IUD expulsions.

In the entire study population general reduction of anxiety was seen at three month and one year, compared to baseline. Concordantly, a better quality of life was generally reported after three months. Regarding overall sexual well-

being, there was no significant change during the follow-up. Better rates in the sexuality questionnaire, i.e. better sexual well-being, were associated with having a relationship, and correlated positively with frequency of intercourse, quality of life, and negatively with anxiety. Contraceptive method appeared to have little effect on overall sexual well-being. However, at three months, IUD users had better scores of sexual well-being, compared to users of other methods.

This study shows that providing TOP and IUD insertion comprehensively at the same unit with minimal delay results in higher attendance at follow-up, higher uptake of IUD and a reduced need of subsequent TOP during one-year of follow-up.

3 Introduction

Fifty years ago, at the United Nations International Conference on Human Rights in Tehran on 13 May 1968, it was declared that “The parents have a basic human right to determine freely and responsibly the number and the spacing of their children”.¹ Yet, even today more than 200 million women lack a contraceptive method in the developing countries.² In many developed countries, a woman’s access to contraception and right to abortion is still being questioned or strictly restricted.

In Finland, the current abortion law dates back to 1970, when abortion based on social grounds was legalized. Based on this law, a woman is granted permission to abortion in practically all cases with a pregnancy under 20 weeks of gestation. Yet, unlike in some other western societies, the abortion is not granted only by request, but must have an indication, and be granted by one or two physicians, or by the National Supervisory Authority for Welfare and Health, depending on the gestational weeks and the indication. Most often (in 93% of all cases in 2017) the indication for abortion is “social distress”, based on the woman’s own notion.³

Since 1972, the communities have been obliged by the law to provide contraceptive counselling visits free of charge for women in all ages.⁴ Providing and subsidizing contraceptive methods are decided on a communal level, and thus the extent of the cost-free services differ greatly across Finland.

In Finland, approximately 9 500 TOPs are performed every year, and their number has been slightly decreasing during the past decade.³ When comparing to other European countries, the incidence is relatively low (8.2/1000 fertile aged [15–49 years] women). However, during the past 15 years the proportion of repeat TOP has been increasing despite the rather easy availability of public contraceptive services. During 2017, 38% of all TOPs were performed in women who had a history of previous TOP, whereas in 2000 the figure was 29%. This is likely to reflect an unmet need of contraceptive counseling and services and poor adherence to contraceptive use in a significant proportion of women.

Repeat surgical TOPs have been associated with elevated risk for preterm delivery and low birth weight in subsequent pregnancies. Although such risks are not associated with medical TOP (MTOP), repeat MTOP can increase the risk of surgical interventions.^{5,6}

In several Northern European countries, including Finland, the method of induced abortion has changed rapidly since the introduction of medical

abortion, i.e. the combination of antiprogestin mifepristone and prostaglandin analogue misoprostol, in the early 2000s. In 2017, 97% of all induced abortions in Finland were medical, which is the highest rate worldwide. In a majority of abortions performed before 9 weeks of gestation, misoprostol can be self-administered at home. Despite many positive aspects of the broadening of alternatives and the individualization of abortion care, the current abortion process produces new challenges for prompt provision of effective contraception, especially that of IUDs. As surgical abortion is becoming a rarity, new strategies of organizing IUD provision following medical abortion need to be developed to promote rapid initiation of effective contraception.

During the past years, long-acting reversible contraception (LARC) methods have become the preferable contraceptive choice in all women.^{7,8} LARCs are not user-dependent, and thus do not require a continuous adherence to use. Therefore, the chance of contraceptive failure due to imperfect use is practically avoided. The efficacy of LARCs, and IUDs in particular, in preventing repeat TOP is well established.⁷⁻¹³

The timing of IUD initiation after medical abortion has been the subject of several recent studies. The key question is how to obtain the shortest possible delay in IUD insertion without unduly increasing the potential risks of expulsion, infection or other adverse events. This is an important issue, not only from the ethical principle to avoid causing harm to a patient, but also from the perspective of optimizing cost-effective contraceptive service provision without the burden of additional visits.

Attendance at postabortal and LARC initiation visits is likely to depend on the service provision system; accessibility of services, flexibility of scheduling appointments, costs of the method and the services, and in some cases, distance and transportation to the clinic. Attitudes, perceptions and skills of the health care professionals also have an impact on how and whom LARCs are recommended and provided to. In countries where contraceptive visits or methods are not subventioned or provided by the society, socioeconomic backgrounds of women affect their choices of contraceptive methods.^{7,14,15}

However, little is known about factors affecting attendance and compliance to LARC provision in a setting where these methods are provided free of charge. When the economic barriers are removed, and even logistics are not an issue, the factors related to the service provision practices and to the background characteristics of the individual become more relevant.

Induced abortion and its possible psychological implications are a matter of disputation. Information and even research regarding this issue are often

politically charged.¹⁶ Efforts to restrict abortion policies are sometimes regarded to be justified by the alleged harms to a woman's mental and physical health and sexuality.^{17,18} An unwanted pregnancy can undoubtedly cause a distressful situation in life and a crisis in a couple's relationship. However, in some cases, abortion can be a solution relieving the distress rather than causing it. Thus, the possible effects of the unwanted pregnancy and those of the abortion should be seen as separate events. Considering the high prevalence of abortion worldwide, relatively little is known about mental and sexual well-being following abortion. One of the goals of the present study was to assess these aspects of health during the first year after an induced abortion.

3.1 Terminology

In this thesis publication, the terms 'induced abortion' and 'termination of pregnancy' are used in parallel in describing a deliberately terminated pregnancy, which does not end in a birth and which results in a death of one or several fetus(es), and in which there is no indication of intrauterine death of the fetus before the procedure.

Using the word 'abortion' has sometimes been criticized for being a negative or stigmatizing expression, while some writers prefer avoiding euphemisms.¹⁹ Clearly, the definitions and terminology in this subject is not standardized.^{20,21} However, I have still chosen to use the word 'abortion'. In my personal opinion, using the word in a sociological, psychological and medical context is a way of destigmatizing the term, whereas strictly avoiding using it would only deepen the stigma.

In the present thesis the term 'first trimester' refers to the first 12 weeks of gestation, i.e. 84 days of gestation.

The term 'sexual well-being' was chosen to be used in this thesis as an umbrella term describing sexual satisfaction, sexual functioning, contentment in the emotional and physical aspects of sexual activity, and the role of sexuality in one's life. Sexual well-being is considered a more concise concept of the broader term 'sexual health', which comprises also sexual rights, prevention of sexually transmitted infections, sexual orientation, and is defined by the WHO as *"a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination*

and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled.”²²

4 Review of the literature

4.1 Induced abortion globally and in Finland

Worldwide, every fourth pregnancy ends in induced abortion. The estimated global annual abortion rate is 35/1000 fertile aged (15–44 years) women, which translates into approximately 56 million abortions every year. In 2010–2014 the abortion rate was 36/1000 fertile aged women in developing countries, and 27/1000 in developed countries (Figure 1).²³⁻²⁵ It is estimated that globally a half of all abortions are unsafe, and that 98% of the unsafe abortions take place in developing countries. Complications caused by unsafe abortions are common. In 2014, 22 500–40 000 deaths occurred due to unsafe abortion. This represents 8–18% of maternal deaths making it one of the leading causes of maternal deaths globally.^{26,27} In developed countries, severe complications of abortions are extremely rare. In the USA, the mortality rate from induced abortion is approximately 0.7/100 000 women.²⁸ It is noteworthy that the incidence of abortion is similar in countries with highly restrictive abortion laws/policies (37/1000) compared to countries where abortion is legal and available at request (34/1000) as seen in Figure 1 and Figure 2.²⁹ It is worth noticing that in countries with restrictive abortion policies, there are no reliable statistics available as most abortions are illegal and unreported. In addition, in these countries or regions, abortion tourism to more permissive nearby countries is common. Thus, the incidences of abortion in such countries are estimates usually based on surveys from samples of women representing various age groups and marital statuses.²⁴ Finland has an exceptional coverage of abortion statistics, thanks to law based obligatory reporting to the registry maintained by the National Institute for Health and Welfare by all instances performing abortions.³⁰

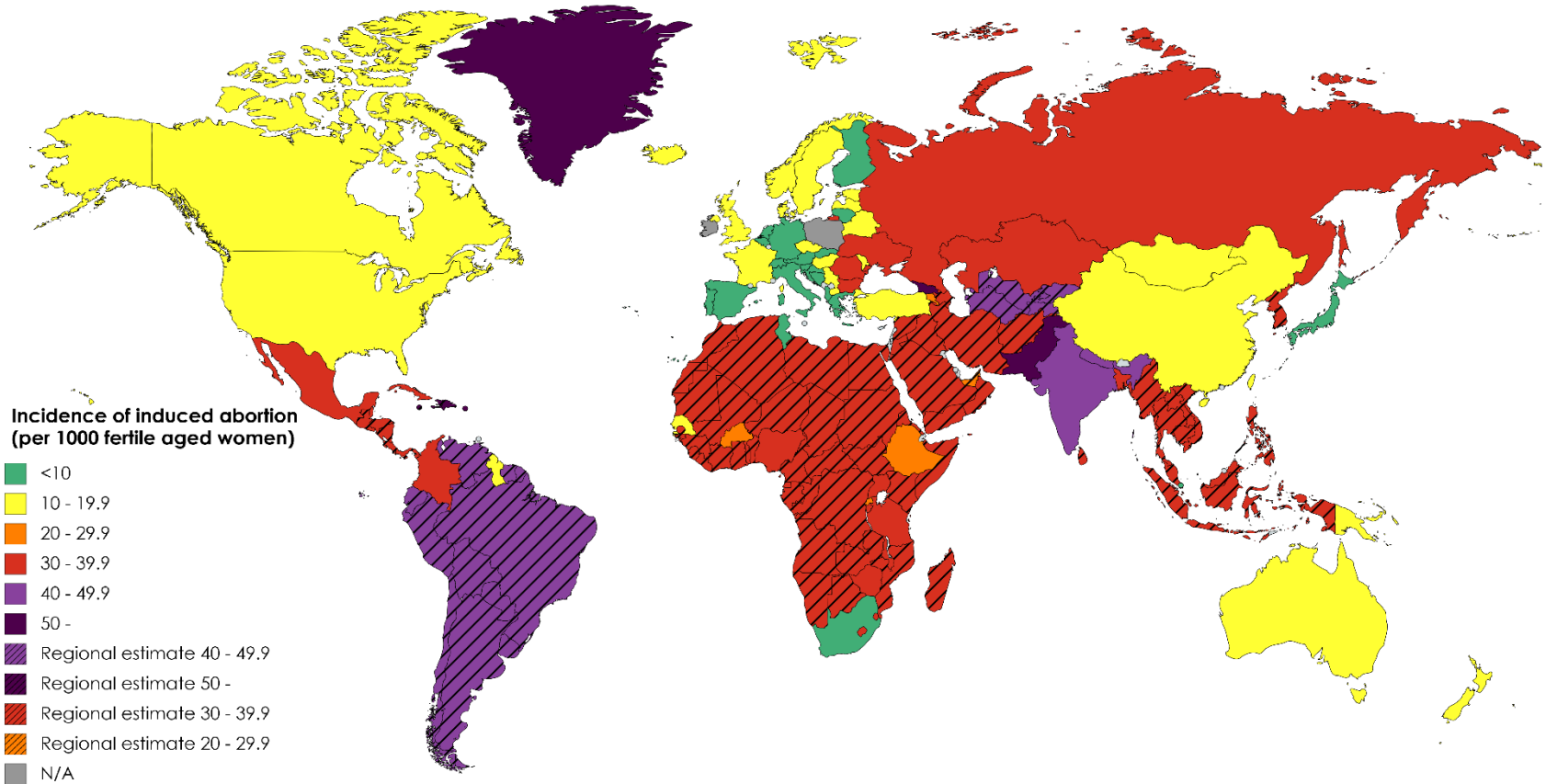


Figure 1. Incidence of induced abortion /1000 fertile-aged women. Sources: WHO, Guttmacher Institute, UN: World Abortion Policies 2013. Created with mapchart.net.

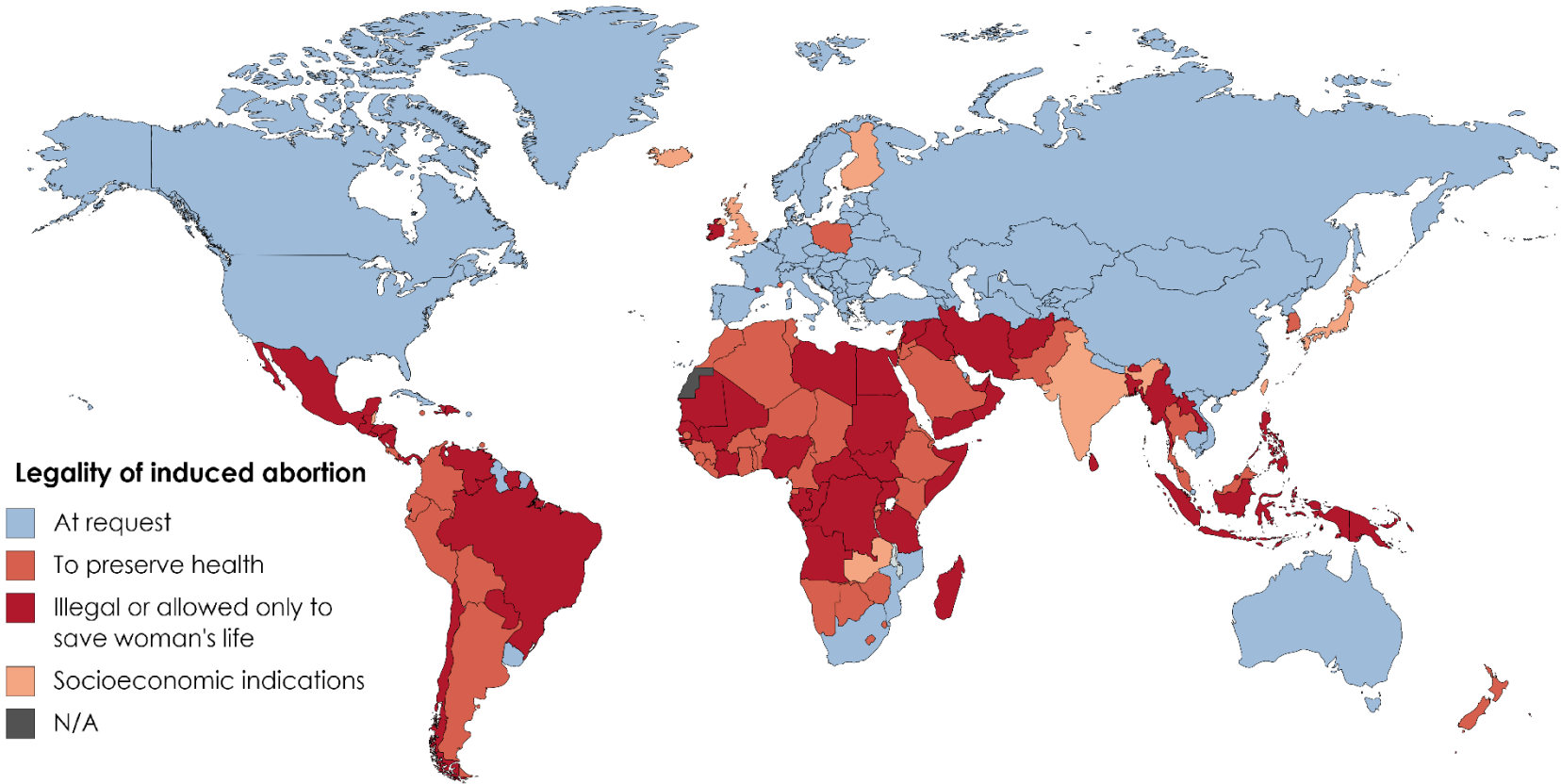


Figure 2. Legality of abortion worldwide in 2018. Sources: WHO, Guttmacher Institute, Center for Reproductive Rights, www.worldabortionlaws.com. Created with mapchart.net.

When looking at the recent Finnish National abortion statistics, a declining trend can be seen in the overall abortion rate, as well as in abortions in the age groups of teenagers and 20–24 years, the latter still presenting the highest abortion rates (Figure 3). On the contrary, an opposite, upward trend can be seen in the abortion rates of women aged 25–39, and in a longer term, in repeat abortions.³

During the past years, contraceptive services of adolescent and young women have been visibly discussed in public, and some municipalities have expanded provision of cost-free contraception in these age groups. This might be one of the reasons behind the declining trends in teenage abortions seen in the national abortion statistics. However, a continuous increase in the rate of repeat abortions clearly indicates that there is a large proportion of women with an unmet need for postabortal counselling and contraception.

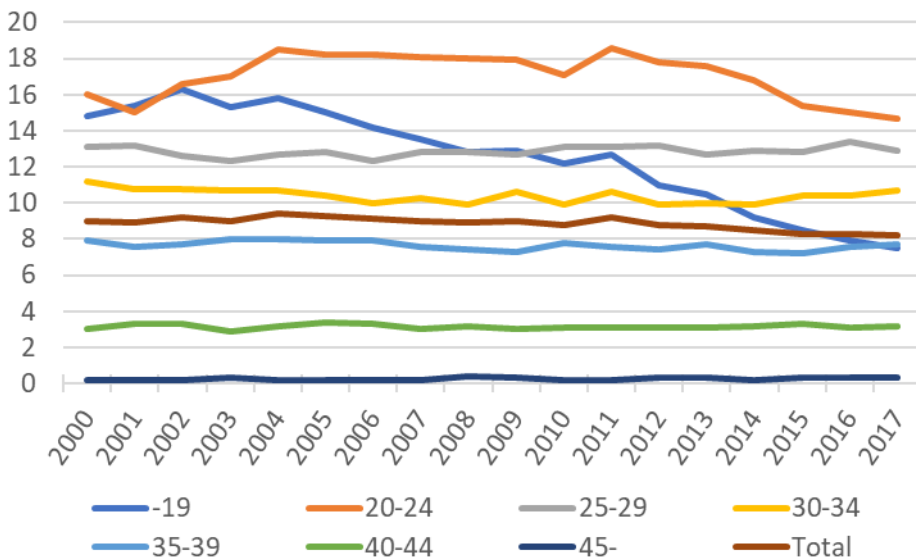


Figure 3. Abortion rate (/1000 women of corresponding age) in Finland according to age groups. (Data derived from: www.thl.fi)

4.1.1 Finnish legislation and policies

According to the Finnish legislation, induced abortion can be performed at permission by one physician before the 13th week of gestation if the woman is aged under 17 or more than 40 years at the time of conception or has given birth to four or more children. Up to 12+0 weeks of gestation, a permission by two physicians is needed for other reasons, such as social indications, risk

for the mother's health caused by pregnancy or delivery, or if the pregnancy is the result of rape or another sexual crime. For abortions performed at 12–20 gestational weeks, and for all abortions performed due to fetal indications, a permission from the National Supervisory Authority for Welfare and Health is required. In cases of severe fetal anomaly, a pregnancy can be terminated at up to 24 weeks.³¹ The principles of the Finnish abortion legislation are presented in Table 1. A pregnancy can be terminated by decision of two physicians regardless of the duration of pregnancy if continuing the pregnancy or giving birth to the child would seriously endanger the woman's life or health.

Table 1. Abortion legislation in Finland

Duration of pregnancy	Age <17 or >40, or >4 children	Social indication²	Fetal indication
≤ 12 weeks	1 physician	2 physicians	2 physicians
12+1 – 20 weeks	Valvira ¹	Valvira	Valvira
20+1 – 24 weeks	-	-	Valvira

¹National Supervisory Authority for Welfare and Health

²Giving birth to the child and the child's care would impose considerable strain on the woman.

In Finland, 93% of all abortions are performed due to social indications in, and 92% take place before 12 weeks of gestation.³ Approximately 99% of TOPs are performed in public hospitals (Anna Heino, personal communication 9.11.2018), to which women can be referred by physicians from the PHC or private clinics. In at least 67% of MTOP performed before 9 weeks of gestation, misoprostol is self-administered at home. (Anna Heino, personal communication 16.11.2018) After TOP, follow-up and contraceptive services after abortion are meant to take place in the referring PHC unit, allowing contraceptive counselling and planning at the time of referral. However, women can choose to use private clinics at own expense for contraceptive services. Some private clinics provide abortion care, for which they must have obtained a registered permission from the National Supervisory Authority for Welfare and Health.

The Finnish National guideline on induced abortion was first introduced in 2001, and last updated in 2013.³² The method of a first trimester TOP is decided individually according to the woman's choice. In 2017, 97% of all TOPs were performed by using the medical method.³ All induced abortions

are reported to the National abortion registry kept by the National Institute for Health and Welfare. The reporting is mandatory by the law.³³

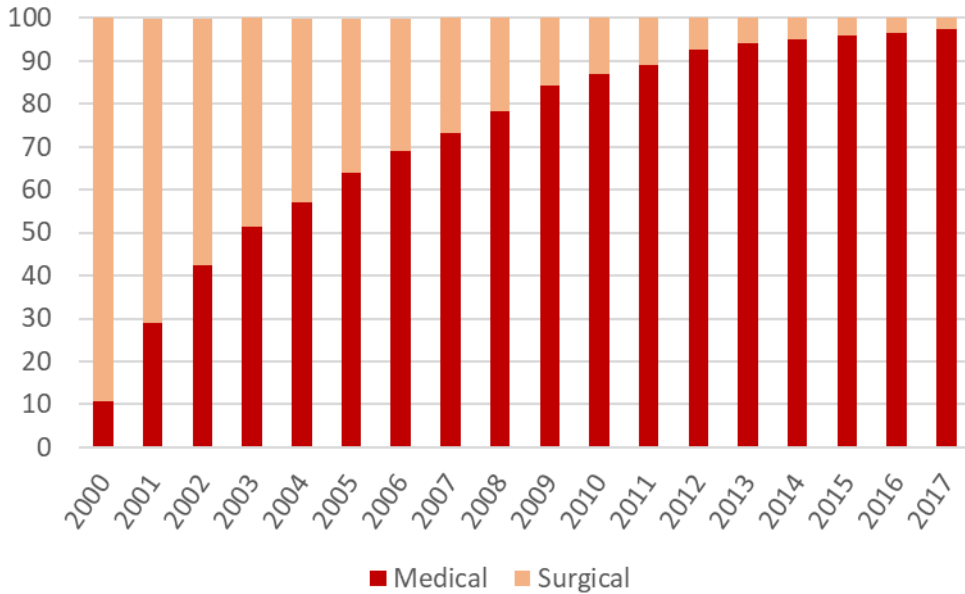


Figure 4. Method of induced abortion in Finland. (Data derived from: Abortion statistics, National Institute for Health and Welfare 2018)

4.1.2 Medical and surgical abortion

In the 1970's, natural prostaglandins were found to induce abortion, but caused intolerable gastrointestinal side-effects. In the early 1980's prostaglandin analogues, such as gemeprost and sulprostone, which were more selective to the myometrium were developed.^{34,35}

The antiprogesterin mifepristone (RU-486) was developed in the early 1980's and applied in clinical testing in 1982, in which the rate of ongoing pregnancy was found to be around 60–80% with monotherapy.³⁶⁻³⁸ In the mid-80's it was found that combining a prostaglandin analogue to the treatment resulted in an efficacy close to 100% with considerably fewer side-effects.³⁸ The medical method of induced abortion by combination of mifepristone and a prostaglandin analogue was legalized in France and China in 1988, followed by Great Britain in 1991 and Sweden in 1992.³⁹

Since the introduction of medical abortion with mifepristone in Finland and several other European countries in 2000, its use has rapidly increased. For the past 15 years it has become the most frequently used method in Finland as well as in many other European countries.^{3,40-42}

According to the current Finnish guidelines on induced abortion, the medical method can be used regardless of the duration of pregnancy within the limits of the abortion law. Medical abortion is performed by administering 200 mg mifepristone orally at the hospital, followed by 800 µg misoprostol vaginally approximately 1–3 days later. In TOP's under 9 weeks of gestation, misoprostol can be self-administered at home. Contraindications for medical abortion are suspected or confirmed ectopic pregnancy, chronic adrenal failure or systemic use of corticosteroids, coronary heart disease, treatment-resistant asthma, clinically significant coagulopathy and difficulty to understand/comprehend and cooperate.³²

In Finland, surgical TOP has traditionally been used in pregnancies up to 12 gestational weeks. Prior to the procedure, the cervix is primed with 400 µg misoprostol orally or vaginally. Cervical dilation followed by suction curettage of the uterus is performed under general anesthesia.³²

4.2 Return of ovarian function and fertility after abortion

The function of the hypothalamic-pituitary-ovarian axis is known to recover rapidly after TOP. Ovulation may occur as early as in 6 days, regardless of the method of abortion or presence of serum hCG.⁴³⁻⁴⁶ The average time from abortion to ovulation is three weeks.^{43,44} It is estimated that 80% of women ovulate within 6 weeks after TOP and 83% ovulate in the first menstrual cycle following TOP.^{43,44}

Sexual activity is also known to resume quickly in most women; in a Danish study, 51% of women had recommenced intercourse by two weeks and 87% by eight weeks after TOP. At eight weeks, the resumption rate was similar also in women with prolonged bleeding, antibiotic treatment or need for uterine evacuation.⁴⁷

4.3 Contraceptive methods; efficacy, adherence continuation

4.3.1 in primary prevention

According to the Finnish National Abortion registry in 2017, two thirds (65%) of women requesting a TOP reported using contraception at the time of conception of the unwanted pregnancy. The most frequently used method was condom (47%).

The efficacy of contraceptive methods is presented by Pearl index, which describes the number of pregnancies per 100 women during one-year use of the method in question. Depending on the source, there is somewhat large variance in the Pearl indexes and continuation rates of contraceptive methods. (Table 2) The differences may reflect variance in the compliance of the population, and possibly a selection bias when assessed in a clinical study population. The continuation rates and Pearl indexes from Finnish population are not available.

Short acting contraceptive methods, such as pills, patches and rings as well as the so-called natural family planning methods require continuous compliance. Inaccurate use of these methods is common, and thus one-year failure rates are high; in withdrawal up to 18%, fertility awareness methods up to 25%, and condoms up to 17%, but also in short acting hormonal contraceptive methods such as oral contraceptives (up to 9%).⁴⁸ Previous studies have shown that an unwanted pregnancy is often preceded by a change from an effective contraceptive method to a less effective one.⁴⁹

Discontinuing the use of contraception during the first year of use is very common especially regarding short acting hormonal methods. It has been reported that up to 76% of women using hormonal contraceptive methods experience side-effects.⁵⁰ The disadvantages and risks of hormonal contraceptives are often feared and overestimated.⁵¹

Table 2. Efficacy and continuation of contraceptive methods according to various sources.

Method	Pearl index Optimal use		Pearl index Typical use		1-year conti- nuation rate (%)	
	A*	B**	A*	B**	A*	B**
OC	0.0–1.3	0.3	0.0–2.2	9	55–59	67
Ring	0.3–1.0	0.3	0.3–1.2	9	56	67
Patch	0.6–1.0	0.3	0.7–1.2	9	50	67
Implant	0.1	0.1	0.1	0.1	74–87	84
Cu-IUD	0.6	0.6	0.8	0.8	84–93	78
LNG-IUS	0.1–0.2	0.2	0.1–0.2	0.2	88–93	80
LARC methods					82–87	
Non-LARC methods					49–59	
Male condom		2		18		43
Withdrawal		4		22		46
Fertility awareness based methods		0.4–5		24		47

A* Summarized from clinical studies: Mansour et al 2010,⁵² Lakha 2006,⁵³ O’Neil 2013,⁵⁴ Peipert 2011⁵⁵. Pearl index indicates the number of pregnancies per 100 women during 1-year use of the method.

B** WHO MEC 2015, source: Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M, editors. Contraceptive technology: twentieth revised edition. New York (NY): Ardent Media; 2011.

The 1-year continuation rates of LARC methods are notably higher than that of non-LARCS. In LARC users, the most common reasons for discontinuing use of the implant are frequent or unpredictable bleedings,^{53,56} whereas IUD removals are most often performed due to inconvenient bleeding patterns or pain,⁵⁷ and this occurs most commonly during the first 6 months of use.⁵⁸ After initiation of LNG-IUS use, irregular bleeding and spotting are common during the first 3–4 months.⁵⁹ Due to progressive reduction of menstrual bleeding, amenorrhea is achieved in 44% of users at 6 months, and in 50% at one year.⁵⁸

Intrauterine contraception is one of the most effective reversible methods of contraception with Pearl index of 0.1–0.2 regarding LNG-IUS and 0.6–0.8 Cu-IUD. (Table 2) IUDs, as well as other LARC methods are more effective

compared to short acting reversible methods, because the typical problems of imperfect use and user-dependent failure are avoided. Typically, the continuation rates at one year are around 88% with LNG-IUS and 84% with Cu-IUDs, compared to that of OCs around 55%.⁵⁵

Worldwide, the most popular method of contraception is female sterilization, whereas IUDs are used by 14.3% of fertile aged, married or in union women.⁶⁰ IUDs are the second most prevalent contraceptive method in the developing countries. In Europe the usage rate is 12%, with a wide range of variation between countries. In Finland the estimated IUD usage rate is 23%, which is the highest in Europe, whereas in the Netherlands, the usage is only 4%.⁶¹ In the USA, the usage rate is as low as 7% but increasing rapidly.⁶⁰⁻⁶²

The overall IUD expulsion rate typically varies around 2–10%.^{63,64} Young/adolescent age (14–19 years), parity and a history of previous IUD expulsions have been associated with a higher risk of expulsion.^{65,66} In some studies the LNG-IUS has shown lower rates of expulsion compared to copper-IUDs.^{63,65}

4.3.2 In secondary prevention

Women undergoing an induced abortion are highly fertile. Based on previous studies, the risk of having a subsequent TOP is approximately 15% in five years.⁹ In Finland the proportion of repeat abortions has been increasing during the past 15 years, despite the declining trend of the overall number of abortions. In 2017 38% of women requesting abortion had a history of one or more previous abortions, and 16% had a previous pregnancy ending in TOP during the past 5 years.³ This implicates suboptimal provision and use of effective contraceptive methods following abortion.

In previous studies, several risk factors for the need of repeat TOP have been identified. These include previous abortion, and especially second trimester abortion, smoking, young age and parity.^{9,67} Previous cohort studies have shown that the choice of contraceptive method predicts the risk of repeat unwanted pregnancy, and the superiority of LARCs has been undeniable.^{7,10,68,69}

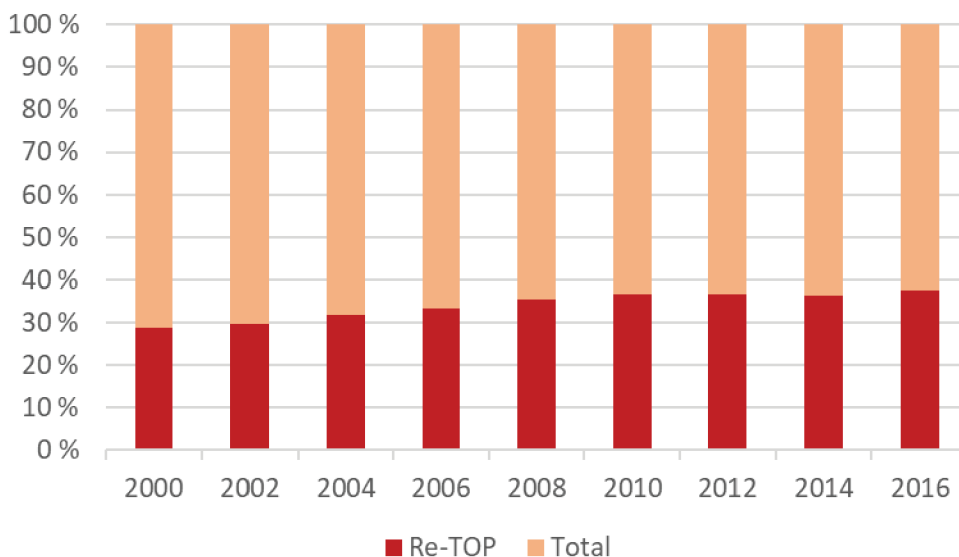


Figure 5. Proportion of repeat abortions in Finland 2000 - 2016. Source: THL Abortion statistics 2000 – 2017 (www.thl.fi).

4.4 Initiation of contraception after termination of pregnancy

IUD insertion at the time of surgical TOP is known to be safe and is recommended by various guidelines, and preferred by women.^{32,70-74}

Following medical abortion, IUD insertion is regarded safe when the abortion is known to be complete.⁷⁰ According to the Finnish guidelines, IUD can be inserted at the follow-up visit 2–4 weeks after TOP.³² In practice, the delay is often even longer, because follow-up is commonly performed by a nurse, and IUD insertion requires an additional appointment with a physician.

Several studies have shown successful interventions of IUD provision 1–3 weeks following MTOP, with no significant increase in rates of expulsions or severe complications.⁷⁵⁻⁷⁷ In a recent Finnish study by Korjamo et al., IUD insertion at 0–3 days interval following MTOP was assessed. Immediate initiation did not increase the rate of severe complications or total expulsion (3%), but the rate of partial expulsion was increased up to 20%.^{78,79}

Oral contraceptives and contraceptive implants can be started immediately at the time of surgical or medical TOP without increasing adverse outcomes of TOP.^{32,70,80,81}

4.5 Barriers in post-abortion care

Several previous studies have shown that attendance at postabortal follow-up visits and at planned IUD insertion visits is low. Typically, half of the women opt out of the follow-up visit,⁸²⁻⁸⁴ and the reported rates of no-show have ranged from 12 to 70%.^{74,77,85} Little is known about possible risk factors of non-compliance. However, it appears that the longer the delay in the follow-up, the lower the rate of attendance.

Some studies have assessed barriers in post-abortion service availability on the provider side. In several countries, these barriers include long distances, logistical and schedule-related issues. In addition, economic reasons play an important role in countries where abortions and postabortal contraception care take place at private clinics, and where contraceptive methods are not subsidized by the society.^{7,86} In such circumstances, the initial costs of IUD can limit the availability, and make the choice of non-LARCs more likely, even if a LARC method might be cheaper in the long term. Previous studies have shown an increased uptake of LARCs when provided free of charge or covered by insurance.^{7,15,86}

In Finland, contraceptive visits in PHC are free of charge for all women throughout the country. The subvention and provision of contraceptive methods varies a lot, as it depends on community-level policy. At the time of the initiation of this study in 2010, Helsinki was the only municipality in the surrounding metropolitan area providing a first LARC free of charge for all women.

In the recent years, LARCs, and especially IUDs have become increasingly common as a first-line contraceptive choice for all women. Also, the attitudes of health care professionals are changing, as LARCs are being recommended as first line contraception for all women, and as new reassuring results on e.g. IUD use among adolescents and nulliparous have been published.⁸⁷⁻⁸⁹

Attitudes and misconceptions concerning LARC methods from the user side, and from the health care provider side play a significant role in the usage rates of LARC methods.⁹⁰ According to several studies, LARC methods are still underused especially among adolescents.⁹¹⁻⁹³ However, when initiated, LARCs are continued more often than oral contraceptives also among young women.⁹⁴⁻⁹⁶ Previous studies have shown 1-year continuation rates ranging from 55% to 90%.^{97,98} Long-acting methods should be preferred especially in this population with a known risk for low adherence and imperfect use. LARCs are recommended as a first-line choice for sexually active adolescents also by the American Academy of Pediatrics.^{10,99}

Inadequate skills or lack of trained physicians can also form a barrier to LARC provision as well as provision of safe abortion.¹⁰⁰⁻¹⁰² In addition, difficulties in scheduling appointments as well as practices of waiting for menstrual periods can decrease rates of LARC initiation. In the recent years, task shifting between health care professionals has become more common and even recommendable especially in the developing countries with a critical lack of skilled professionals.¹⁰³⁻¹⁰⁵ According to WHO, abortion care and IUD insertion by trained nurses or midwives is feasible and recommendable.

4.6 Recovery after abortion

Verifying the outcome of TOP by serum hCG measurement is advised in guidelines, whereas routine pelvic examination or ultrasonography is not regarded necessary except for suspected complications.^{32,70} Ultrasonography is poor in detecting residual tissue, and the need for surgical evacuation cannot be predicted by endometrial thickness.^{106,107}

During the first few weeks following medical abortion, bleeding and abdominal pain are common.^{108,109} However, serious complications are rare. In abortions performed at up to 9 weeks of gestation, the rate of continuing pregnancy is <0.5%.^{110, 111} The overall rate of adverse events after MTOP is around 20%, and according to some studies higher than the rate of adverse events related to surgical abortion.¹¹² The reported rates of adverse events depend on how they are defined, and also, how well established the medical method is in the study site. Rates of adverse events following surgical or medical abortion according to previous literature are shown in Table 3.

Table 3. Rates of adverse events following surgical or medical TOP.

	Bjørge¹⁰⁸	Knudsen¹⁰⁹	Suhonen¹¹³	Ashok¹¹⁰	Niinimäki¹¹⁴		White¹¹⁵
	Medical	Medical	Medical	Medical	Medical	Surgical	Surgical
Infection	-	-	-	-	1.7	1.7	0–11.6
Infection requiring surgical evacuation	0.5	2.0%	-	-	0.8	0.6	-
Infection requiring intravenous antibiotics	-	-	-	-	-	-	0–7.7
Hemorrhage	-	-	-	-	15.6	2.1	0–4.7
Bleeding requiring evacuation	0.0	4.0%	1.0	0.2	2.9	0.9	-
Bleeding requiring blood transfusion	-	0	-	-	-	-	<0.1
Residual tissue	-	-	2.6	-	-	-	-
Incomplete abortion	-	-	-	2.3	6.7	1.6	-
Incomplete abortion requiring reabrasion	4.1	-	5.0	1.6	5.9	0.4	<0.1–8.0
Adverse events total	-	-	-	-	20.0	5.6	-

4.6.1 Mental well-being

The possible effects of abortion on a woman's mental health are often disputed, and sometimes a matter of argumentation colored by stigmatizing opinions. Mental health after abortion is difficult to assess reliably, and designing a reasonable study is challenging, as reliable data on mental health prior to the unwanted pregnancy is usually not available. Latest research on the matter shows mainly a neutral effect.¹¹⁶⁻¹¹⁹ In addition, some evidence implies that possible changes in mental health following abortion are related to the distress caused by an unwanted pregnancy rather than the abortion itself. Furthermore, social and mental problems are likely to be overrepresented in women deciding to end the unwanted pregnancy.¹²⁰⁻¹²²

4.6.2 Sexual well-being

Only few studies have assessed sexual life and well-being after abortion. This subject is difficult to examine reliably, because neither subjective nor objective data on sexual well-being before the unwanted pregnancy is hardly ever accessible. In addition, sexuality, and to an even greater extent, abortion are matters of cultural differences, norms and taboos, due to which all studies must be seen in the context of the cultural backgrounds they relate to. However, in most studies performed in developed countries, the majority of women report no effect on sexuality.¹²³⁻¹²⁵ Some studies have suggested a short-term negative effect in a minority (10–20%) of participants in terms of decreased sexual interest or problems in sexual functioning.^{47,124,126-128}

Previous studies assessing the effects of IUD on sexuality have shown that intrauterine contraception has little or no effect on sexual well-being and functioning. In some studies, the effect was mainly positive.¹²⁹⁻¹³¹

5 Aims of the study

- To evaluate the safety of early IUD insertion after MTOP. (I)
- To assess the success of planned early IUD insertion following MTOP, and factors affecting it. (I)
- To compare the effectiveness of two different ways of providing contraceptive services, and to assess factors affecting rates of attendance at follow-up and IUD usage in women randomized to different service tracks. (II)
- To assess the efficacy of routine provision of intrauterine contraception after first trimester abortion in reducing the need for subsequent abortion. (III)
- To assess anxiety and quality of life after induced abortion, and factors affecting it. (IV)
- To assess sexual well-being after induced abortion, and factors affecting it. (V)

6 Subjects and methods

6.1 Study design

This randomized, controlled trial was conducted at Kätilöopisto Hospital, Department of Obstetrics and Gynecology, Helsinki University Hospital in collaboration with the Department of Social Welfare and Health of the City of Helsinki. The primary outcome was to assess the effect of early routine provision of intrauterine contraception on the incidence of repeat TOP during five years follow-up.

The secondary outcomes were incidence of repeat TOP during the first year of follow-up, complications related to MTOP and early IUD insertion, compliance to post-abortion care, the success of planned early insertions, and mental and sexual well-being after the TOP. In this thesis, the focus is on the first year of follow-up.

The participants were recruited between October 2010 and February 2013 among women requesting a first trimester abortion, who were at least 18 years of age and planning future intrauterine contraception. Only residents of Helsinki were included in the study as the City of Helsinki collaborated in planning and carrying out the study, and provided the IUDs. Women with intrauterine anomaly, acute pelvic infection, or a PAP-smear change requesting immediate interventions were excluded. The baseline characteristics of the participants are presented in Table 4.

The power calculation was made with the assumption of a 15% risk for subsequent unwanted pregnancies during five years, and a 50% reduction in the risk after provision of intrauterine contraception. Using the log-rank test and with a one-year accrual time, for a 5-year total study time with 80% power and a 5% significance level, we needed at least 350 women in each group.

During the recruitment period, altogether 5245 women were assessed for eligibility, 2305 of them were found eligible, and 1139 (49.4%) were interested in intrauterine contraception. To cover up for possible loss to follow-up, a total of 751 women were recruited and randomized. Three women chose to continue the pregnancy after randomization, and thus, 748 women were included in the analyses.

Table 4. Baseline characteristics of the study participants. The data are presented as n (%) unless stated otherwise.

	Intervention Group n = 375 (%)	Control Group n = 373 (%)
Age (years); median (IQR)	27 (22 to 33)	27 (23 to 33)
Days of amenorrhea; median (IQR)	57 (49 to 66)	56 (49 to 65)
Daily smoking	188 (50.1)	189 (51.4)
Regular use of alcohol	275 (73.3)	286 (77.9)
History of drug abuse	7 (1.9)	13 (3.5)
BMI (kg/m ²); median (IQR)	23 (21 to 26)	23 (21 to 26)
History of pregnancy	261 (69.6)	247 (67.3)
History of delivery	187 (49.9)	175 (46.9)
History of induced abortion	174 (46.4)	153 (41.0)
Type of induced abortion		
Medical	307 (81.9)	299 (80.2)
Surgical	68 (18.1)	74 (19.8)
Type of planned contraception		
Cu-IUD	26 (6.9)	24 (6.4)
LNG-IUS	349 (93.1)	349 (93.6)
Marital status		
Married	71 (18.9)	52 (13.9)
Cohabiting	102 (27.2)	92 (24.7)
Single	202 (53.9)	229 (61.4)
Contraception used at the time of conception		
Combined hormonal contraceptives	45 (12.0)	49 (13.1)
Progestin-only pill	12 (3.2)	9 (2.4)
Cu-IUD	-	1 (0.3)
Condom	159 (42.4)	135 (36.2)
Other	8 (2.1)	14 (3.8)
None	151 (40.3)	165 (44.2)

6.1.1 Interventions and follow-up

Altogether 748 women were randomized into two groups; 375 in the intervention and 373 in the control group. The randomization was performed by using the permuted block method. The group assignments were kept in sealed envelopes, which the study nurse opened after recruitment. The investigators did not take part in the randomization process.

Women in the intervention group received an IUD at the hospital providing the abortion either during surgical TOP or at a follow-up visit 1–4 weeks after medical TOP. Women choosing a surgical TOP had a follow-up visit 1–4 weeks after the TOP to ensure correct placement of the IUD, or to have an IUD inserted if not placed during the procedure. The type of the IUD (either the 52mg levonorgestrel-releasing intrauterine system, LNG-IUS, Mirena® or a copper-IUD, Nova-T®, both manufactured by Bayer Ag [Turku, Finland] was chosen according to the woman's preference. Three months after the TOP, all women in the intervention group had an appointment with the study nurse to assess recovery and to ensure proper placement of the IUD by visualizing the IUD strings. Ultrasonography was performed by a study physician if the strings appeared missing or too long. In cases of expulsion, a new device was inserted.

Women in the control group were prescribed oral contraceptives and advised to contact the PHC for further follow-up and IUD insertion, according to current normal practice. The City of Helsinki provided the IUD free of charge if the woman had not used intrauterine contraception previously, thus the planned IUD was cost free for the majority of women in the control group.

All women were advised to contact the study hospital in cases of suspected or diagnosed complications related to TOP. Women in the intervention group were advised to contact the study personnel in case of any IUD related problems.

One year after the index TOP, all women were invited to a follow-up visit performed by a gynecologist at the Centralized Family Planning Clinic of the City of Helsinki. Figure 6 shows the one-year follow-up flow chart. In addition, all participants were followed-up for one year via the hospital databases, and data on the subsequent TOP's were obtained from City of Helsinki databases and the Abortion registry of the National Institute for Health and Welfare.

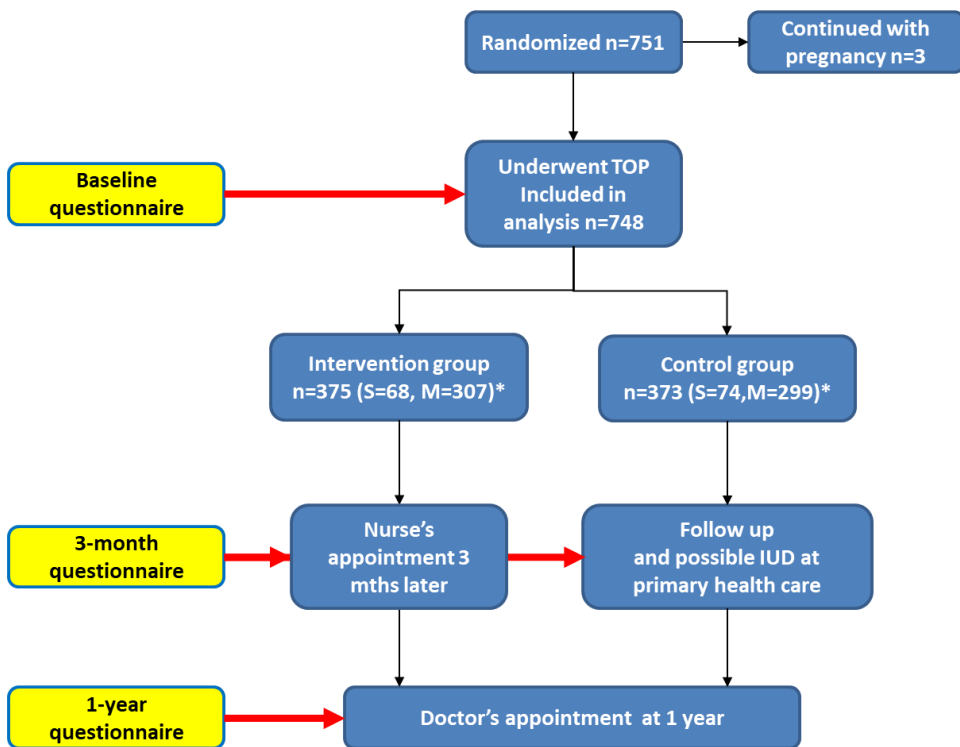


Figure 6. Flow chart: 1-year follow up and timing of questionnaires.

6.1.2 Questionnaires

All participants were asked to fill in a questionnaire at the time of the recruitment, as well as at three months and one year after the TOP. The questionnaire forms consisted of validated inquiries regarding anxiety (STAI), quality of life (EQoL) and sexual well-being (MFSQ) as well as additional questions regarding health, smoking, alcohol consumption, medication, contraception, new pregnancies, relationship status and working status.

The State-Trait Anxiety Index (STAI) is widely used in evaluating the level of anxiety. It consists of 40 items in total, half of which composing the state subscale measuring current anxiety, and the other half composing the trait subscale measuring proneness to anxiety in general. In this study, the state scale of the STAI was used to assess the level of anxiety at three time points, and to evaluate changes in it during the follow-up time. The state subscale consists of 20 items rated on a 4-point Likert scale, higher score indicating greater level of anxiety. A cut point of 40 was used as indicative of clinically relevant anxiety.¹³²

Euro Quality of Life Questionnaire (EQ-5D) is a standardized instrument for measuring the perceived general state of health. We used its three-level version (EQ-5D-3L) to examine quality of life among our study participants. In this questionnaire, five health dimensions are assessed; mobility, self-care, usual activities, pain or discomfort and anxiety or depression, each divided into three levels of perceived problems. The gained information was converted to an EQoL index by using a specific algorithm with a weight for each dimension. In addition, a visual analogue scale measuring the perceived state of health on a scale from 0–100 (EQ-VAS) was used.^{133,134}

In assessing sexual well-being, a Swedish version of the McCoy Female Sexuality Questionnaire (MFSQ), modified by Wiklund et al. was used.¹³⁵ The original McCoy Female Sexuality Questionnaire (MFSQ) has been developed by Norma McCoy in the 1990's, and originally composed of 19 questions rated on a 7-point Likert scale. We used its shorter 9-item form, which is also validated and found suitable for different age groups.¹³⁶ We analyzed two questions considering contentment with a regular partner separately, taking into account only those respondents who reported having a partner. The remaining seven questions were divided into three dimensions: sexual interest (frequency of fantasies, enjoyability of sex in general, contentment with current frequency of sex), sensations during sex (arousal, orgasms) and physical problems (dyspareunia, vaginal dryness).

6.2 Study on the success of early IUD insertion after medical termination of pregnancy (I)

The aim of this study was to compare the numbers of complications and adverse events during three months after medical abortion in both groups as well as to assess the reasons for possible delay or failure in IUD initiation after MTOP. There were 606 women included in this analysis (307 in the intervention and 299 in the control group), as the women choosing surgical TOP were excluded. The hospital database was accessed to analyze all additional visits to the hospital due to TOP-related causes (such as bleeding, incomplete abortion or infection) or possible IUD-related causes (such as infection or expulsion). In the intervention group, the timing of the IUD insertion was assessed, and factors affecting possible delays were analyzed. In addition, all IUD expulsions were analyzed. Adverse events were analyzed according to intention-to-treat analysis (ITT), whereas complications related to early IUD insertion (within 4 weeks) were assessed on per-protocol basis (PP). The timing of TOP-related adverse events was also analyzed in both groups.

6.3 Study on non-compliance (II)

In this analysis, the rates of non-attendance at planned follow-up and IUD use within three months after medical abortion were assessed. Women choosing surgical TOP were not included in this analysis, as nearly all of them received an IUD at the time of the abortion, and thus IUD usage in these women would not have reflected their compliance to aftercare. The study population was the same as in study I, with an exception of one participant, whose method of abortion was changed from medical to surgical due to heavy bleeding immediately after administration of misoprostol. Thus, 605 women were included; 306 in the intervention and 299 in the control group.

To assess non-compliance and non-attendance at the follow-up visits and IUD insertions as well as contacting the PHC as planned in the control group, data was collected from the databases of the City of Helsinki.

We analyzed non-attendance and IUD usage rates in both groups in relation to various background factors to identify possible predicting factors of non-attendance or non-compliance to IUD insertion.

6.4 Study on subsequent termination of pregnancy (III)

The primary objective of this study was to assess the effect of IUD contraception on the incidence of subsequent TOP during the first year after the index TOP, when the IUD is initiated early and provided in the same unit that provides the TOP, compared with the present practice when IUD is provided in the PHC. Data on subsequent TOP was collected from the Finnish national abortion registry kept by the National Institute for Health and Welfare. In addition, the electronic databases of the hospital district of Helsinki and Uusimaa were accessed to assess all cases where TOP was requested but eventually not needed, such as blighted ovum, spontaneous miscarriage or ectopic pregnancy diagnosed at the time of assessment for TOP. All analyses were performed on intention-to-treat (ITT) basis as well as on per protocol (PP) basis.

The results presented in this publication differ slightly from the ones published earlier in the article III. Due to errors in the procedure dates and uncertainties in the data, the number of women requesting a subsequent TOP during one year was mistakenly reported as 29 instead of 26. Three cases included in the first analysis actually occurred more than 365 days after the index TOP. One of these cases was a subsequent TOP and two were miscarriages. This thesis is written based on the correct figures. In addition, the corrected results are presented in the Corrigendum.

6.5 Study on mental health and quality of life (IV)

In this study, anxiety and quality of life of all the participants were assessed during the first year after abortion by analyzing the data collected from the questionnaires filled at baseline, as well as three months and one year after the abortion. Changes in the STAI-score and the EQoL index between the three timepoints was assessed. In addition, possible background factors explaining differences in the scores were examined.

6.6 Study on sexual well-being (V)

The goal of this study was to assess possible changes in sexual well-being during the first year after abortion. In addition, possible effects of various background factors (age, parity, history of pregnancy or TOP, smoking, alcohol consumption, relationship status and mental or physical conditions) associated with differences in McCoy scores were analyzed.

Contraceptive method was taken into account only at three months and at one year, but not at baseline. At the time of the baseline questionnaire many of the women had stopped using any contraception after finding out about the pregnancy. In addition, the hormonal milieu of early pregnancy might have interfered with possible effects of hormonal contraception at that timepoint.

6.7 Study approvals and registrations

The trial was approved by the Ethics Committee of the Hospital District of Helsinki and Uusimaa (HUS 260/13/03/03/2009), as well as the City of Helsinki (10-1138/054), and it was registered at www.clinicaltrials.gov (NCT01223521). An approval to carry out the study was granted by the Hospital District of Helsinki and Uusimaa (§12/30.03.2010). Approval to use personal-level data was obtained from the National Institute for Health and Welfare as required for registry-based studies in Finland (THL/1479/5.05.00/2013).

6.8 Statistical analysis

All analyses were performed with the SPSS software, versions 18–24 (IBM corp., Armonk, NY). Statistical significance was defined as $p < 0.05$. Chi-square or Fisher's exact tests were used as appropriate for independent nominal data. The distributions of continuous variables were analyzed and compared

by using the Mann-Whitney U-test for skewed data (Studies III and V). Survival analysis were performed by using Kaplan-Meier analysis (Studies II and III). Logistic regression was used to calculate odds ratios (OR) with a 95% confidence interval (95%CI) (Studies I, II). In assessing correlations of continuous variables, Spearman correlation factors were calculated (Study V). In study IV, a comprehensive analysis of missingness at random was performed to account for the missing data from the women not returning the questionnaires.

7 Results

7.1 Study on the success of early IUD insertion after MTOP (I)

In this secondary analysis the factors affecting the success of early initiation of intrauterine contraception after first trimester medical TOP were assessed. The indications, possible treatments and timing of all additional hospital visits of the study participants during three months after TOP were analyzed.

There were no significant differences in the number of unscheduled visits due to bleeding in the intervention and the control group (20 [6.5%] vs. 23 [7.7%], $p=0.572$). Heavy bleeding requiring surgical evacuation of the uterus occurred in 9 (2.9%) vs. 11 (3.7%) women, respectively ($p=0.607$). Regarding all infections, the differences between the two groups were not statistically significant; an infection was diagnosed and treated with antibiotics in 29 (9.4%) women in the intervention and 17 (5.7%) in the control group ($p=0.081$). Intravenous antibiotics were used for 10 (3.3%) and 9 (3.0%) women, respectively. Thus, there was no significant difference in the incidence of severe infections either ($p=0.861$). However, oral antibiotics were prescribed significantly more often to women in the intervention group (19 [6.2%] vs. 8 [2.7%], $p=0.036$).

Residual tissue was suspected significantly more often among women in the intervention group ($n=72$ [23.5%]), compared to the control group ($n=30$ [10.0%], $p<0.001$). Additional misoprostol was administered to 52 (16.9%) women in the intervention vs. 9 (3.0%) women in the control group ($p<0.001$). Of the women who received additional misoprostol, 21 (40.4%) vs. 3 (33.3%) were diagnosed with persistent residual tissue and were further scheduled for surgical treatment, respectively. In total, uterine evacuation due to suspected residual tissue was performed in 40 (13.0%) women in the intervention vs. 24 (8.0%) women in the control group ($p=0.045$).

Altogether 91.2% ($n=280$) of the women in the intervention group received an IUD within three months, and 67.2% of them during the first four weeks, as planned initially (Figure 8). Delayed insertions ($n=46$) were due to suspected or diagnosed residual tissue, or infection ($n=43$), or non-attendance at the first scheduled appointment ($n=3$). In addition, twelve women received an IUD at the time of surgical evacuation of residual tissue.

During the three-month follow-up, 126 (41.0%) women in the intervention and 52 (17.4%) in the control group had an additional hospital visit. In the

control group, 38 (12.7%) women had an intervention due to TOP-related cause, most of which (60.5%, n=23) took place within the first two weeks following abortion. In the intervention group, altogether 82 (26.7%) women had an intervention due to TOP-related cause, only 20 (24.4%) of which within two weeks' time interval after TOP (Figure 7).

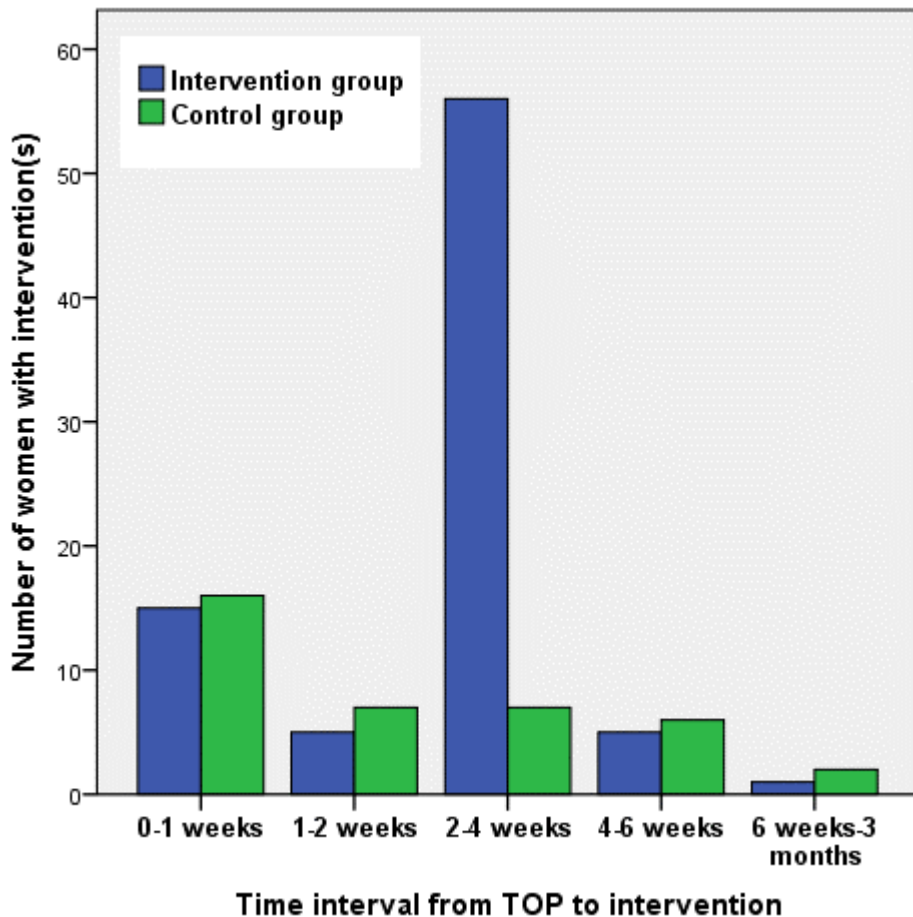


Figure 7. Number of women with a suspected or diagnosed condition or adverse event judged to require intervention (medical or surgical treatment of residual tissue, antibiotics, blood transfusion) according to time interval from TOP to intervention.

7.2 Study on non-compliance (II)

In the intervention group, 6.9% (n=21) women did not attend the planned follow-up visit 1–4 weeks after the abortion. Seven women who attended the follow-up changed their mind and chose not to have an IUD inserted but continued with oral contraceptives instead. Thus, 9.2% (n=28) women in the intervention group did not receive an IUD within three months. (Figure 8)

In the control group, 22.4% (n=67) women did not have any contact to the PHC. Altogether 34.1% (n=102) women did not attend a follow-up visit or have a telephone follow-up. During three months, only 26.4% (n=79) had an IUD inserted. Of the 197 women who did have a follow-up, 183 of which by in-person visit, only 36.0% (n=71) received an IUD within three months.

The difference between the intervention and control groups was significant in attendance (OR 7.03 [CI 95% 4.25–11.63] $p<0.001$), and in receiving an IUD within three months (OR 27.65 [CI 95% 17.35–44.06] $p<0.001$).

In the intervention group, non-attendance at follow-up was significantly associated with smoking (OR 2.66 [CI 95% 1.01–7.06] $p=0.049$), history of drug abuse (OR 5.90 [1.07–32.41] $p=0.041$), history of pregnancy (OR 10.16 [1.34–76.84], $p=0.025$), history of previous abortion (OR 5.68 [1.86–17.30] $p=0.002$), and STAI score >40 at baseline, implicating clinically relevant anxiety (OR 4.10 [1.16–14.47] $p=0.028$).

In the control group, the predicting factors associated with non-attendance were fewer: only history of pregnancy (OR 2.38 [1.37–4.14] $p=0.002$) and history of abortion (OR 1.97 [1.21–3.21] $p=0.006$) were significantly associated with non-attendance.

Women with previous pregnancy OR (4.26 [1.25–14.46] $p=0.020$) and/or previous abortion (OR 4.07 [1.67–9.88], $p=0.002$) were less likely to receive an IUD in the intervention group. There were no significant background factors associated with non-compliance for IUD insertion identified in the control group.

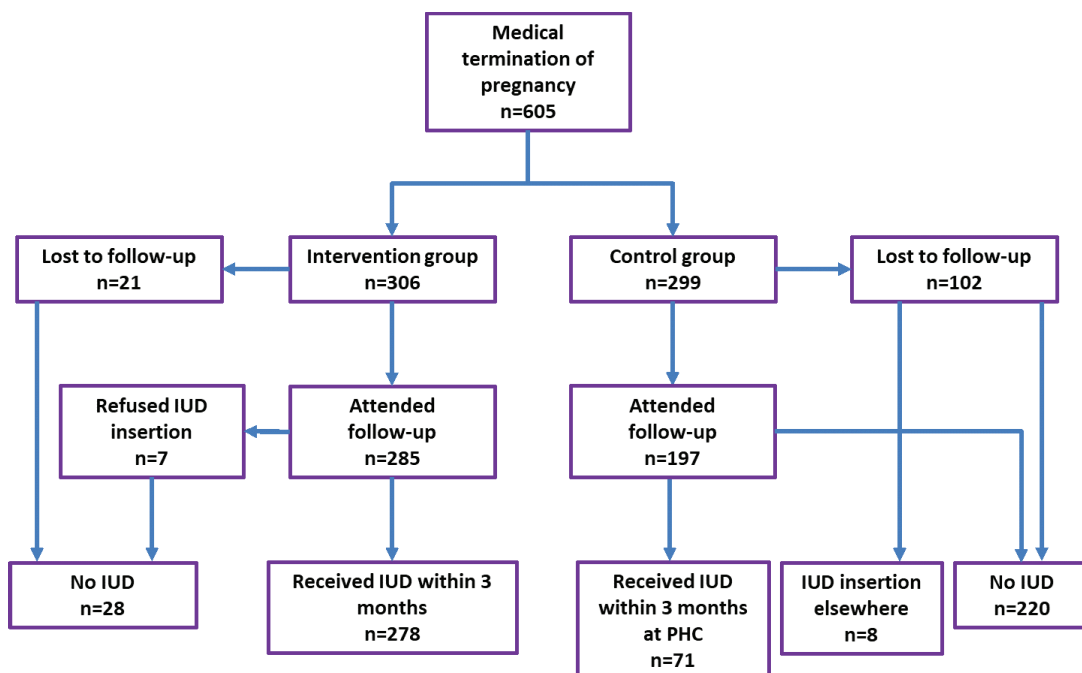


Figure 8. Compliance to follow-up and IUD insertion among participants choosing MTOP (ITT-basis).

7.3 Study on the need of subsequent TOP (III)

According to ITT analysis, altogether 26 women (3.5%) presented at the hospital with a request for TOP during the first year of follow-up. The rate of requested TOP was 1.9% (n=7) in the intervention and 5.1% (n=19) in the control group, and the difference was statistically significant ($p=0.020$). Three women were diagnosed with a miscarriage and two women with an ectopic pregnancy, and finally 23 (3.1%) women underwent an abortion. Of these women, 6 (26.1%) belonged to the intervention group and 17 (73.9%) to the control group (Table 5). The median time from the index abortion to the subsequent abortion was 8 months (IQR 6–11). Nearly half (n=12) of the women undergoing a subsequent abortion were not using any contraceptive method at the time of conception, and none of them were using intrauterine contraception.

In the control group, sixteen women received an IUD at the time of surgical TOP, contrary to the study protocol. Accordingly, 27 women in the intervention group did not receive the IUD as planned. These cases were regarded as protocol violations and excluded from the PP analysis.

Table 5. Women with requested re-TOP during first year of follow-up.

	Intervention group (n=375)	Control group (n=373)	HR (95% CI)	<i>p</i>
Requested TOP, n (%)	7 (1.9%)	19 (5.1%)	2.8 (1.2–6.6)	0.020
Repeat TOP, n (%)	6 (1.6%)	17 (4.6%)	2.0 (0.8–5.1)	0.140

The cumulative proportion of women without subsequent TOP at one year was 98.4% in the intervention group and 95.4% in the control group ($p=0.019$) (Figure 9). The intervention reduced the number requested TOP by more than half, and the rate of repeat TOP by almost two thirds.

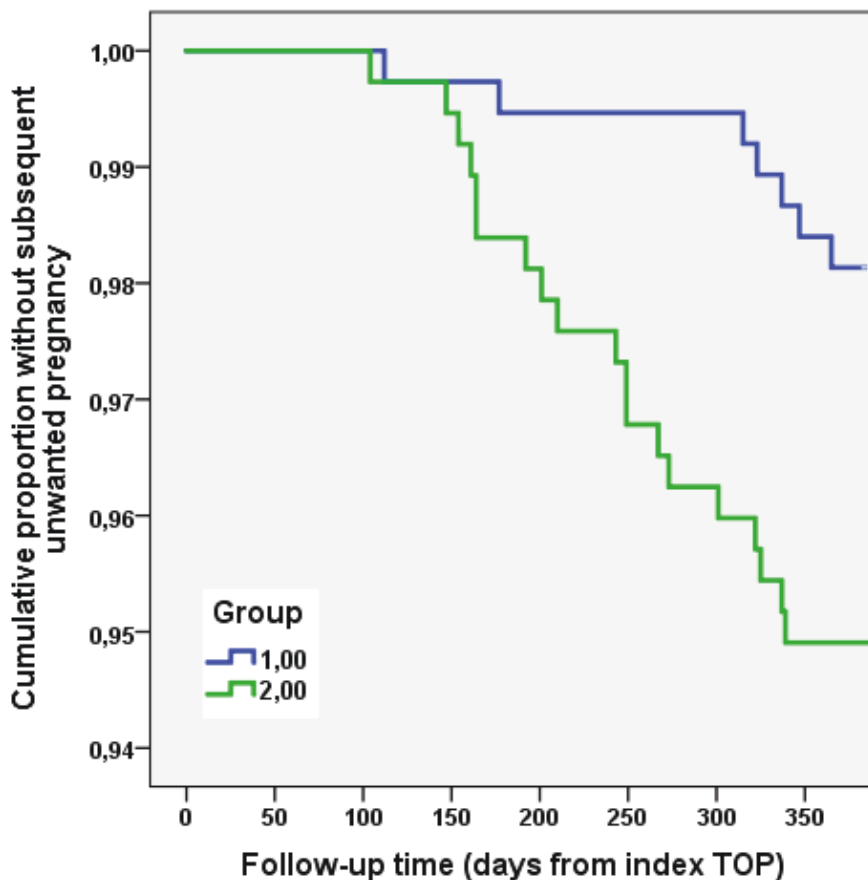


Figure 9. Survival curve of the study subjects showing proportion of women without subsequent unwanted pregnancy during one-year follow-up. Group 1= intervention group, Group 2= control group.

7.4 Study on mental health (IV)

Response rates of the study questionnaires were 95.6% (n=715) at baseline, 63.1% (n=472) at three months, and 51.5% (n=385) at one year. Baseline data and at least one of the follow-up questionnaires were available in 69.0% (n=516) cases, which were included in the analysis. Due to the relatively low response rate, the background factors of the respondents and non-respondents were analyzed. The missingness was found to be a random event, and thus the available data could be used in the analyses.

Clinically relevant anxiety was found in 58% of the respondents at baseline, in 38% at three months and in 42% at one year. The overall STAI-scores were significantly lower at three months (38.79 ± 13.31 , $p < 0.001$) and one

year (38.78 ± 13.75 , $p < 0.001$), compared to those at baseline (44.58 ± 13.63). Similarly, QoL had significantly improved after three months (index: 0.81 ± 0.19 , $p = 0.001$; EQ-VAS: 74.19 ± 16.75 , $p < 0.001$) and one year (index: 0.81 ± 0.19 , $p = 0.002$; EQ-VAS: 73.63 ± 18.11 , $p < 0.001$) compared to baseline (index: 0.76 ± 0.21 ; EQ-VAS: 67.80 ± 19.55). This positive change was evident in women reporting a clinically relevant level of anxiety at baseline. However, such change was not seen in women reporting normal STAI-scores (< 40) at baseline, in whom the anxiety levels remained the same during the one-year follow-up. In addition, the higher the STAI score was at baseline, the higher the scores at the 3-month and 1-year follow-ups were, despite the changes in individual scores after TOP.

The levels of anxiety had a significant negative correlation with QoL at all time points (baseline: $r = -0.62$, $p < 0.001$; 3 months: $r = -0.63$, $p < 0.001$; 1 year: index: $r = -0.64$, $p < 0.001$). Smoking (OR 1.65, $p = 0.026$) and history of psychiatric morbidity (OR 2.74, $p = 0.001$) were significant predictors for higher anxiety at three months.

7.5 Study on sexual well-being (V)

The response rates to the McCoy questionnaires were the same as described above (study IV). The overall McCoy index remained practically unchanged during the follow-up (Mean 36.5 [SD: 5.58], 36.4 [5.70], 35.8 [6.71]). There were no significant changes in the overall scores between the three time points in any of the sub-dimensions either. McCoy scores at baseline had a significant positive correlation to the scores at three months and one year ($r = 0.58$, $p < 0.001$; $r = 0.52$, $p < 0.001$).

When looking at background factors associated with differences in total McCoy scores, anxiety (STAI index) had a significant negative correlation at all timepoints ($r = -0.20$, $r = -0.36$, $r = -0.37$, $p < 0.001$), whereas frequency of intercourse had a significant positive correlation ($r = 0.50$, $r = 0.46$, $r = 0.42$, $p < 0.001$). Women reporting living in a relationship had significantly better scores at all time points, compared to single women (Figure 10). Reported quality of life (EQoL) had a mild but significant positive correlation to the overall McCoy scores throughout the follow-up time ($r = 0.20$, $r = 0.20$, $r = 0.27$, $p < 0.001$).

Associations between chosen method of contraception and McCoy scores were few; at three months, IUD users reported better scores of total McCoy index (37.0 [8.0], $n = 346$ vs. 36.0 [6.0], $n = 109$, $p = 0.022$), as well as scores of sexual interest (15.0 [5.0], $n = 352$ vs. 14.0 [4.0] $n = 110$, $p = 0.022$), compared to

the rest of the study population. However, the difference was not seen at one year. Women using hormonal contraception reported lower rates in the dimension of arousal and orgasms at one year, compared to women with non-hormonal methods or no contraceptive use (median 10.0 [IQR 5.0], n=285 vs. 11.0 [4.0], n=84, $p=0.017$).

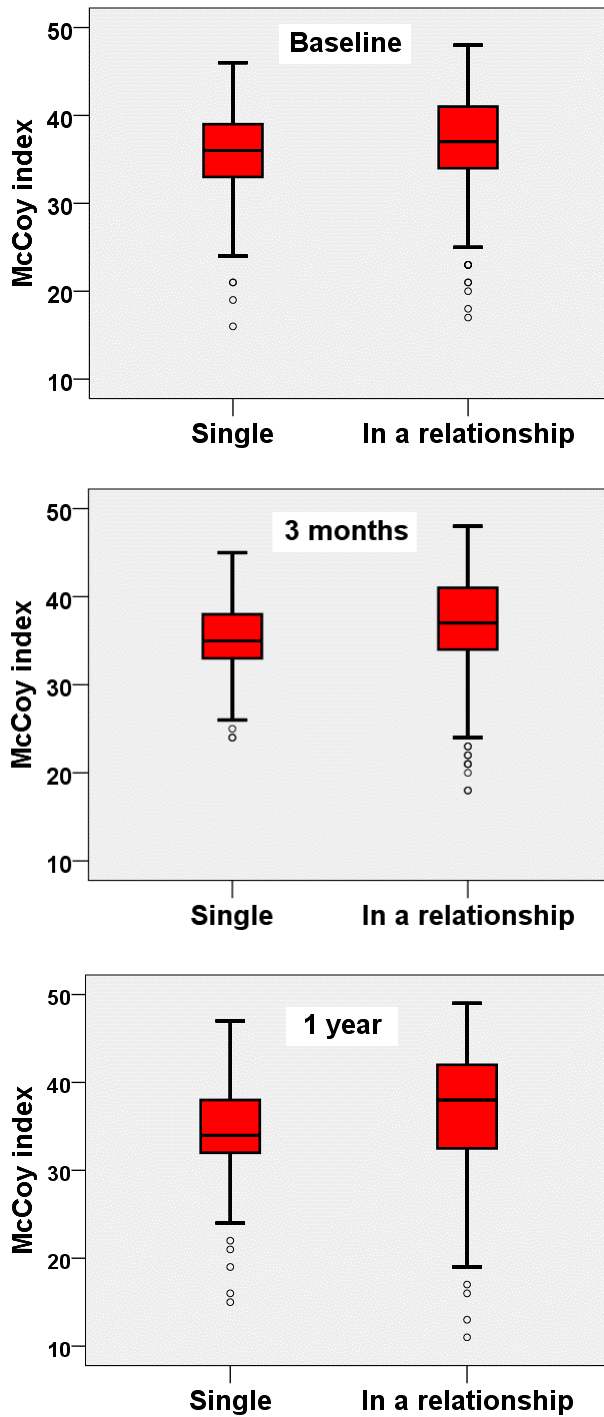


Figure 10. McCoy index at three timepoints according to relationship status.

8 Discussion

8.1 Contraceptive choice and the risk of subsequent termination of pregnancy

Women undergoing a TOP are generally healthy and highly fertile. They have usually experienced a failure of contraception, as majority of the women have been using some contraceptive method at the time of conception.³

The contraceptive efficacy of various methods differs greatly. LARCs are known for their high contraceptive efficacy which does not require constant user adherence. Thus, LARCs have become the recommended first line contraceptive choice for women at all ages according to various international guidelines.^{99,137,138} However, IUDs still remain underused especially among young women.^{72,91-93} At the time of TOP, women might be especially motivated to choose an effective method.¹³⁹ In the eligible population assessed for recruitment in this study, 49% of women were interested in intrauterine contraception.

The efficacy of IUDs also in preventing repeat unwanted pregnancy has been demonstrated in several cohort studies.^{9,11-13,69} This effect was clearly shown also in study III, which is one of the first randomized studies examining this subject. The study intervention – i.e. provision of IUD as part of the abortion care – more than halved the incidence of subsequent request for TOP (1.9%), compared to the control group (5.1%). None of these unwanted pregnancies occurred during IUD use or following an unnoticed expulsion. These results have significant clinical relevance in indicating that integrating IUD provision to TOP care is effective in reducing the need for subsequent TOP.

8.2 Safety and timing of IUD insertion after termination of pregnancy

Following TOP, fertility and sexual activity resume rapidly, and thus early initiation of effective contraception is essential in avoiding subsequent unwanted pregnancy. Prompt initiation of IUDs after TOP results in higher usage and user contentment, compared to delayed insertion.^{71,77,83,140} IUD insertion at the time of surgical TOP is safe and recommendable also in order to avoid additional visits.^{70,140} However, as MTOP has become more common, identification of the optimal timing of IUD insertion following MTOP has become more relevant.

In a recent study by Korjamo et al., immediate insertion of IUD following MTOP resulted in high IUD usage and reduced risk for subsequent pregnancy

without increasing the risk of severe complications. However, the risk of partial expulsion was increased.^{78,141} IUD insertion after a short interval (5–10 days) following MTOP has been successful and uncomplicated in several previous studies without elevated risk of expulsion.⁷⁵⁻⁷⁷ In the present study, IUDs were mainly inserted 1–4 weeks following MTOP in the intervention group. In study I, we found that the rates of expulsion or severe complications were not increased by early initiation of IUD. The rate of IUD expulsion during three-month follow-up was similar to that reported in previous studies following immediate insertion at the time of surgical TOP (5%).¹⁴² In some previous studies, obesity and thickness of endometrium have been associated with higher risk of IUD expulsion or malposition.^{143,144} However, in our study population, expulsion could not be predicted by BMI, endometrial thickness or uterine sound measure at the time of insertion. The only factor associated with higher risk of expulsion was longer duration of gestation at the time of the TOP.

Among women in the control group, and thus with no routinely scheduled hospital visits, 60% of the cases of residual tissue were detected within 14 days following MTOP. This indicates that most of the complications that need intervention occur early, which is in concordance with previous studies.¹¹⁰ Based on the timing of the adverse events in study I, an IUD insertion at approximately 2 weeks after MTOP might be optimal in minimizing the risk of further complications. On the other hand, rapid resumption of ovulation and sexual activity favors earlier insertion, possibly within the first week after TOP. Among women with high risk of not attending a scheduled follow-up, immediate insertion might be feasible despite the higher risk of expulsion, if the women are informed about the risk. Optimizing the timing of IUD insertion would require evaluation of the woman's individual risk of dropping out vs. risk of expulsion.

8.3 Verifying the outcome of medical termination of pregnancy

It has been reported previously that the use of ultrasonography as means of follow-up after MTOP may lead to overdiagnosis of residual tissue.^{106,113} Thus, use of serum hCG measurement in verifying the outcome of the TOP is recommended. This was seen on the present study, too, despite the fact that the ultrasonography was performed by physicians experienced with MTOP. In study I, IUD insertion was delayed in 15% of cases in the intervention group, mostly due to suspected residual tissue based on ultrasonographic examination. Compared to the control group, additional misoprostol was

administered significantly more often in the intervention group. Moreover, it was found rather ineffective, as 40% of these women were further treated by uterine evacuation. In light of these results, it is evident that a large proportion of these women likely received an unnecessary treatment. Differentiating a clinically relevant residual tissue from hematoma by ultrasonography is challenging. In many cases the uterine contents found in the ultrasonography at the follow-up visit might have dissolved in time without any interventions.¹⁴⁵ However, women in the intervention group were intended to receive their IUD within 1–4 weeks, and thus the time frame set by the study protocol might have affected the women's wishes and the physician's decisions to solve the problem rapidly to avoid a longer delay and several extra appointments.

Recent research has shown encouraging results on successful self-assessment of the outcome of TOP by using low-sensitivity urinary hCG tests.¹⁴⁶⁻¹⁴⁸ At least in a selected study population, it seems that after counselling, women are competent in detecting possible ongoing pregnancy and in recognizing symptoms of possible complications themselves.^{149,150} Self-assessment might be feasible as an alternative for serum-hCG testing and telephone follow-up, saving women from the trouble of going to laboratory, and possibly enabling health care professionals to engage more time for the women having complications or requiring special attention.

8.4 Compliance to post-abortion care

The attendance to follow-up – either by telephone or an in-person visit - was notably low (66%) in the control group despite the fact that these women participated in a clinical trial and the follow-up was planned according to the current practice. Similar or even lower rates of attendance have been reported in previous studies.^{82,151} On the other hand, an exceptionally high attendance (93%) was observed in the intervention group, where the appointment took place in the same unit that provided the abortion care. In the entire study population, only few factors were found to associate with non-attendance. Women with previous pregnancies and/or previous TOP, and/or clinically relevant levels of anxiety at baseline were more likely to opt out. In the control group there were even fewer predictive factors; previous TOP and/or delivery. Difficulty in predicting non-attendance in this group suggests that the poor attendance in the current practice is rather due to the nature of the service provision than the characteristics of the study participants.

In the intervention group, the women who dropped out despite being actively contacted by the study nurse were likely a very selected population. Belonging to this small proportion of women was predicted by smoking, history of drug abuse and clinically relevant levels of anxiety, which can be seen as indicators of poor socioeconomic status.^{152,153}

We found a significant difference between the intervention and control groups in the compliance to the planned IUD insertion following medical TOP, even though all participants had expressed an interest in intrauterine contraception at the time of recruitment. A majority of the women in the control group could have received the IUD free of charge from a PHC unit relatively close to their home. Thus, economic reasons or long distances do not explain the differences in this group. A notable difference was also seen in returning the questionnaires and attending the one-year follow-up visit. This might be explained by the extra care and active contacting provided by our study nurse for the participants in the intervention group.

Due to loss-to-follow-up, exact data on 1-year IUD continuation rates are not available in the study population. However, 60% of women belonging to the intervention group attended the planned 1-year visit, and 89% of them were using IUD at that time. This is likely a selected group of women presenting an optimistic usage rate compared to the entire intervention group. Further, in the intervention group, it is hard to evaluate exactly how important the timing of the IUD insertion was in achieving the high IUD usage rate, as the participants were actively contacted for re-booking in case of non-attendance.

8.5 Contraceptive services after termination of pregnancy

According to the current practice in Finland, contraceptive services, including post-abortion IUD provision, are to be provided by municipalities at their PHC units. Thus, following TOP, women are normally advised to contact the PHC to make an appointment for contraceptive counselling and/or IUD insertion. Oral contraceptives are commonly prescribed as a bridging method to be initiated immediately and continued until IUD insertion. Most women are initially referred from the same PHC unit to the hospital for the TOP, which allows contraceptive planning at the time of referral. However, it is common that women do not have a contact person at PCH, and they may face a different health care professional at every appointments and telephone contact.

A follow-up at 2–4 weeks after TOP, to be performed by a nurse if there are no suspected complications, is recommended in the national guidelines on TOP. Further, an IUD can be inserted in the PHC at a follow up visit or at the time of first menstrual period.³² In practice, the recommended follow up comprises often a serum-hCG sample and a telephone contact or an in-person visit with a nurse, and thus a later appointment with a physician is needed for IUD insertion. This practice often produces a delay, which is likely to increase the rate of non-attendance. In most PHC units, IUD insertions are performed by only few physicians, which can result in difficulty of scheduling appointments for IUD insertions.

In previous studies with a TOP to insertion delay of approximately 3 to 6 weeks, the rates of receiving the planned IUD has ranged from 19% to 86%.^{74,77,83,85} In our study, 75% of the planned IUD insertions in the intervention group took place within four weeks after MTOP, as planned, and all women who attended follow-up and were willing to have an IUD received it by three months. Thus, IUD initiation occurred in 91% of the women in this group.

Of the entire control group, only one in four women received an IUD within three months. Further, only less than 40% of the women in the control group who had a contact to the PHC received an IUD within 3 months after TOP. Thus, non-attendance in this group was likely affected by difficulty in scheduling despite attempting to book an appointment. However, altogether 22% of the women in the control group never contacted the PHC for follow-up. This reflects a low adherence to post-abortion care and contraceptive services when it depends on one's own initiative and when the unit providing the abortion is different than the one providing the post-abortion care. It is of notice that in real life, the compliance is likely to be even lower, compared to the study setting with highly motivated women.

In light of these findings it may be suggested that providing abortion and contraceptive services comprehensively in the same health care unit, a better rate of attendance and IUD usage could be achieved, and the risk of subsequent unwanted pregnancy reduced. It might also be useful to have a contact person at the health care unit to achieve lower threshold of contacting. One of the key findings in our study was the effectiveness of the centralized early IUD provision compared to the current practice of IUD provision in the PHC, in reducing the need of subsequent TOP.

In this study, the unit providing the services was a university hospital. However, it can be questioned whether it might be reasonable to arrange the MTOP and IUD services at PHC. Shifting or sharing tasks between health care

professionals in family planning care have shown encouraging results in some studies and should be considered as an option in arranging more flexible easy-access contraceptive care.^{103,104} Considering the Finnish guidelines and current practice, an IUD insertion might more probably take place at a follow-up visit in a reasonable time frame if the insertions could be performed by nurses or midwives, too.

8.6 Recovery after termination of pregnancy

Physical recovery after TOP under legal and safe circumstances is, with rare exceptions, undeniably uncomplicated and rapid. However, mental recovery following TOP is sometimes a matter of controversy. Moreover, sexual well-being after TOP is underexamined, given the commonness of TOP worldwide. Most of the studies assessing mental health after TOP show mainly neutral effects.^{118,154-156} However, psychiatric morbidity and suicidality has been found to be more prevalent among women undergoing a TOP, compared to base population,^{116,157} suggesting the possibility of common underlying factors predisposing to these outcomes.

In study IV we found that the levels of anxiety were significantly reduced, and quality of life improved within three months in the entire study population. This improvement was evident among women reporting clinically relevant anxiety at baseline (58%). A notable proportion of women (40%) reported a good quality of life and low levels of anxiety throughout the study. Based on this, it may be stated that an unwanted pregnancy or TOP does not cause a remarkable prolonged distress in all women. The results might indicate that TOP is rather a relief to a distressful situation than a cause for distress. However, women with history of psychiatric morbidity and/or high levels of anxiety at the time of abortion were more likely to report persisting elevated levels of anxiety and lower quality of life during the follow-up. It might be recommendable to schedule an in-person follow-up for women with a known history of psychiatric morbidity in order to recognize the possible need for additional support. Providing follow-up and mental support by one's own initiative might not be sufficient in this group of women, considering also that clinically relevant anxiety is associated with the risk of non-attendance (Study I).

In assessing sexual well-being after TOP, we found that the overall McCoy score remained unchanged during the one-year follow-up. In this study, women reporting low levels of anxiety, high quality of life, having a partner and frequent sexual activity had higher scores in the McCoy questionnaire. This suggests that sexual well-being is not notably altered following TOP, but

rather strongly associated with indicators of overall well-being. Sexual well-being is connected to general mental and physical health, and it should be kept in mind that women might wish to discuss these matters with health care professionals at any in-person visits. Women who are prone to anxiety or mental health problems might need special attention or counselling in sexual health issues.

As reported also in previous studies, the choice of contraceptive method had little effect on sexual well-being.^{129,158,159} At three months, women choosing intrauterine contraception reported higher McCoy scores compared to women using other methods. This could be explained by lessened concern of an unwanted pregnancy when using an effective contraceptive method. However, at one year the difference was no longer seen.

Recovery after an induced abortion is a multifaceted process affected by various background factors, societal circumstances and previous mental and physical health of the individual. The challenge is to recognize the women in need for special attention and more intensive care, such as those benefitting from psychological support or counselling on sexual health.

8.7 Strengths and weaknesses of the study

The randomized design of the trial, and the large sample size are strengths. The randomization and power calculation for this study population were performed for a follow-up time of five years, based on an assumed risk for repeat TOP. However, a significant difference in the incidence of subsequent abortion between the randomization groups was found already after one year.

In terms of parity and history of abortion, the study population is representative of the Finnish population in general, which can be considered as an additional strength. Moreover, there were no significant differences in the background characteristics of the randomization groups.

The median age of the study population was 27 years (IQR 23 to 33). In light of the National abortion statistics, most of the abortions are being performed in the age group 20–24. This may reflect the perception, either by study participants or by e.g. referring physicians, that intrauterine contraception would be more suitable for parous women. However, it is worth noticing that this study is likely to reflect the situation at the time of recruitment (2010–2013), and the attitudes and perceptions concerning IUS use have probably changed under the past years along with updated guidelines and encouraging results of recent studies.^{137,138,160-162}

8.7.1 Study I

This substudy was performed by analyzing adverse events among women participating the primary contraceptive trial, according to which the power calculations were made. Thus, the population was not sufficient for evaluating the incidence of rare events, such as uterine perforation. This can be seen as a shortcoming of this secondary analysis. In addition, at the time of analyzing the results of this substudy, data of all PHC visits due to TOP-related indications and early IUD insertions were not available. However, all participants were advised to contact the hospital in case of suspected complications, and thus any adverse event requiring a hospital visit could be detected from the hospital databases.

There was no significant difference in the incidence of infections requiring intravenous treatment between the randomization groups. However, oral antibiotics were prescribed more often in the intervention group, half of them at the study follow-up visit, based on clinical evaluation at the time of IUD insertion. In the control group, oral antibiotics might have been prescribed from the PHC for women with mild symptoms that did not require referral to the hospital, and thus, this data was not available in the analysis of this study. The difference in oral antibiotic administration between the two groups can partially be explained by the experimental nature of the study intervention and the effort of being on the safe side in avoiding the possible risk of uterine infection in case of suspected mild bacterial infection during IUD insertion. Some of these treatments might not have been described at all if the IUD insertion had taken place at a later timepoint.

8.7.2 Study II

This substudy might be criticized for the different follow-up procedures in the two groups. However, one of the aims of the study design was to compare the current service provision to a more comprehensive one. Indeed, a significant difference was seen in the rates of attendance and IUD use between the two groups, although all women were voluntary participants in a clinical study and interested in IUD contraception.

8.7.3 Study III

This study was initially planned for a five-year follow-up. Thus, the power calculations were performed based on the assumed incidence of subsequent TOP during five years. However, a significant difference in the request for subsequent TOP was seen already after the first year of follow-up.

The number of protocol violations in this study was quite high, especially regarding IUD insertions during surgical abortion in the control group.

However, the difference between the groups remained significant in the per protocol-analysis.

8.7.4 Study IV and V

In both of these studies the outcome was measured by validated questionnaires, which is a strength. Typically for this group of women and a sensitive topic, the adherence and thus also the response rate were rather low. Following analysis of the missing data, the missingness was found to be a random event in relation to the background factors, and thus the available data could be used.

We were able to assess changes in sexual well-being and mental health during the abortion process, and one year onwards. In addition, we could analyze how different background factors relate to the women's well-being after abortion. However, to reliably assess the effect of abortion, a reference group with no unplanned pregnancies or abortions would have ideally been needed. Still, it would be difficult to differentiate the effect of the unplanned pregnancy from the effect of abortion. As seen in light of some previous studies, designing a study for comparing women undergoing an abortion with another group of women is problematic; a group of non-pregnant women would lack the possible effects of an early pregnancy, a group of women with a planned pregnancy would likely have different backgrounds and situation of life (and relationship status). Even without any reference group, a baseline questionnaire before the unwanted pregnancy would be needed to assess the actual effect of the unwanted pregnancy and/or the abortion.

9 Conclusions

The following conclusions can be drawn:

- Early initiation of intrauterine contraception following medical TOP is safe and does not increase the risk of IUD expulsion or severe complications. (I)
- Providing IUD insertion as an integral part of TOP services leads to higher rate of attendance, IUD usage, and significantly decreases the incidence of subsequent unwanted pregnancy during the first year. (II, III)
- Non-attendance at post-abortion follow-up is associated with history of previous deliveries and history of TOP. (II)
- Predictive factors for low compliance in post-abortion care are few, and thus providing an option for IUD insertion as an integral part of abortion care is justified for all women. (II)
- Recovery after TOP is an individual process and is influenced by various background factors. In most women, mental health and quality of life are normalized rapidly, and not severely affected in the long term. Women with history of psychiatric morbidity, or high levels of anxiety at the time of TOP present a minority that might be more prone to adverse mental long-term effects. (IV)
- Sexual well-being is multifactorial and associated with mental health, good quality of life and being in a relationship, but not significantly affected by TOP or the choice of contraceptive method in majority of women. (V)

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12 Summary in Finnish

12.1 Tausta

Raskauden keskeytys on yksi tavallisimmista toimenpiteistä maailmanlaajuisesti. Arviolta joka neljäs raskaus keskeytetään, mikä tarkoittaa lukumääräisesti n. 56 miljoonaa keskeytystä vuosittain. Suomessa raskaudenkeskeytysten prevalenssi on verraten varsin matala, ja pysynyt pitkään samalla tasolla. Vuonna 2017 tuhatta fertiili-ikäistä (15–49 vuotiasta) naista kohden Suomessa tehtiin 8,2 raskauden keskeytystä. Näistä reilu kolmannes tehtiin naisille, joille oli aiemmin tehty yksi tai useampi keskeytys. Uusintakeskeytysten osuus kaikista keskeytyksistä onkin ollut nousussa viime vuosina, vaikka ehkäisyn saatavuus on yleisesti ottaen hyvä, ja ehkäisypalvelut ovat lakisääteisesti maksuttomia kuntien järjestäminä. Uusintakeskeytysten määrästä päätellen nykyiset ehkäisypalvelut eivät tavoita riittävän hyvin osaa naisista raskaudenkeskeytyksen jälkeen. Hedelmällisyys palautuu keskeytyksen jälkeen pian; ensimmäinen ovulaatio tapahtuu keskimäärin kolmen viikon kuluttua. Siksi uusien ei-toivottujen raskauksien estämiseksi nopeasti aloitettu tehokas raskauden ehkäisy on tärkeää.

Pitkävaikutteiset, palautuvat raskauden ehkäisy menetelmät (kierukat ja ehkäisykapseli) eivät vaadi päivittäistä muistamista, ja virheellisen käytön riski on minimaalinen. Ne ovat kiistatta osoittautuneet tehokkaimmiksi ehkäisy menetelmiksi myös raskauden keskeytyksen jälkeen. Tutkimusten mukaan kierukkaehkäisy vähentää uuden ei-toivotun raskauden riskiä jopa kolmikertaisesti verrattuna muihin ehkäisy menetelmiin, kuten ehkäisy pillereihin ja estemenetelmiin.

Viimeisen 15 vuoden aikana Suomessa valtaosa raskauden keskeytyksistä on tehty lääkkeellisesti, ja vuonna 2017 enää 3% tehtiin kirurgisesti. Monista hyvistä puolistaan huolimatta tämä kehitys asettaa haasteita kierukkaehkäisyn aloitukselle; kaavinnan yhteydessä kierukka on voitu useimmiten asettaa välittömästi. Viimeisimpien tutkimusten valossa välitön (alle 72h) kierukan asetus lääkkeellisen raskauden keskeytyksen jälkeen on turvallista, mutta lisää osittaisen ekspulSION riskiä. Tutkimuksissa, joissa kierukka on asetettu noin viikon kuluttua ekspulsiORISKIN ei ole todettu poikkeavan myöhempään asetusajankohtaan verrattuna.

12.2 Tutkimusasetelma

Oma tutkimuksemme on viisivuotinen seurantatutkimus, johon osallistui 748 ensimmäisen raskauskolmanneksen keskeytykseen tulevaa täysi-ikäistä, kierukkaehkäisystä kiinnostunutta helsinkiläistä naista. Heidät satunnaistettiin kahteen eri hoitopolkua noudattavaan ryhmään.

Interventioryhmään kuuluville asetettiin kierukka sairaalassa joko kaavintakeskeytyksen yhteydessä tai seurantakäynnillä 1–4 viikkoa lääkkeellisen keskeytyksen jälkeen. Kontrolliryhmään kuuluville aloitettiin tablettiehkäisy ja heitä ohjattiin nykyisen vallitsevan käytännön mukaisesti ottamaan yhteyttä omalle terveysasemalle jälkitarkastusta ja kierukkaehkäisyn aloitusta varten.

Osallistujien terveydentilaa, ahdistuneisuutta, koettua elämänlaatua ja seksuaalista hyvinvointia seurattiin kyselylomakkein tutkimuksen alkaessa, sekä kolmen kuukauden ja vuoden kuluttua. Keräsimme kolmen kuukauden ajalta tiedot kaikista raskaudenkeskeytykseen tai kierukkaan liittyvistä sairaalakäynneistä tarkastellaksemme komplikaatioita ja mahdollisia varhaiseen kierukkaehkäisyn aloitukseen liittyviä haittavaikutuksia. Vuoden seurannan jälkeen keräsimme tiedot uusista raskaudenkeskeytyksistä THL:n raskaudenkeskeytysrekisteristä sekä sairaalan potilastietojärjestelmästä. Tarkastelimme lisäksi jälkitarkastusten ja suunniteltujen kierukanasetusten toteutumista sekä niihin vaikuttavia taustatekijöitä randomisaatioryhmissä.

12.3 Tulokset

Varhainen kierukan asetus lääkkeellisen raskaudenkeskeytyksen jälkeen ei lisännyt vakavien komplikaatioiden eikä ekspulsion riskiä kolmen kuukauden seurannan aikana. Interventioryhmään kuuluvat naiset kävivät merkittävästi useammin jälkitarkastuksessa ja heille asetettiin todennäköisemmin kierukka kolmen kuukauden aikana kuin kontrolliryhmään kuuluville.

Tutkimusinterventio vähensi merkittävästi uusien keskeytysten tarvetta ensimmäisen seurantavuoden aikana verrattuna nykyiseen normaaliin ehkäisy palvelukäytäntöön.

Tutkimukseen osallistujien elämänlaatu koheni ja ahdistuneisuus väheni yleisesti tutkimuksen aloitusajankohdan ja kolmen kuukauden seurannan välillä, ja säilyi sen jälkeen oleellisesti ennallaan vuoden ajan. Merkittävä osa naisista koki kliinisesti relevantin tasoista ahdistusta raskauden keskeytyksen aikoihin, ja näillä naisilla ahdistuksen lieventyminen kolmen kuukauden aikana näkyi selvimmin.

Seksuaalinen hyvinvointi ei tutkimuspopulaatiossamme muuttunut oleellisesti vuoden seurannan aikana. Raskaudenkeskeytyksellä tai sen jälkeen aloitetulla ehkäisyllä ei näytä olevan pitkäaikaista oleellista merkitystä koettuun seksuaaliseen hyvinvointiin. Sitä vastoin siihen ovat yhteydessä koettu hyvä elämänlaatu, vähäinen ahdistuneisuus, parisuhde sekä seksuaalinen aktiivisuus.

13 Original publications