Does Lidocaine 10% Spray Reduce Pain during IUCD Insertion? A randomized Controlled Trial

Thesis

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Chapter (1):

IUCD

Introduction

Background

For more than 30 years, women throughout the world have been using the intrauterine contraceptive device (IUCD) as their method of contraception. It is, in fact, the most commonly used reversible method among married women of reproductive age worldwide. According to recent estimates, almost one in five (or 153 million) married contraceptive users is currently using the IUCD ***(Salem, 2006).***

The popularity of the IUCD may be due in part to the high level of satisfaction among IUCD users. Women who use the IUCD are more satisfied with their choice of contraception than are those using other reversible methods (99% versus 91% for pill users), according to research conducted in the United States ***(Forrest, 1996).*** Data compiled from a US-based study and an international World Health Organization (WHO) study suggested that about 92% of women are still using the Copper T 380A at 1 year after insertion ***(Association of Reproductive Health Professionals [ARHP], 2004).***

Formative research shows that some attributes that IUCD users like most about the method are that it:

- Offers highly effective, long-term protection against pregnancy, with immediate return to fertility upon removal.
- Has no hormonal side effects.
- Is inexpensive over time (no costs after initial cost).
- Is convenient; does not require daily action on the part of the user, or repeated clinic visits for supplies ***(Rivera et al., 2006)***.

Despite the overall popularity of the IUCD, the bulk of IUCD use is concentrated in relatively few countries. Most notable among these is China, where almost 92 million (or 60%) of the world's married IUCD users reside. In many countries in Eastern Europe, Central Asia, the Near East, and North Africa, at least half of the women who use contraception use the IUCD. In other parts of the world, however, the IUCD is among the least used methods. In India, for example, 3% of married women of reproductive age are IUCD users; in North America, that percentage is even lower at 2% ***(Salem, 2006)*.**

Old Myths, New Research

One of the main reasons that the IUCD is under-used in some parts of the world may be that clinicians and potential IUCD clients lack accurate, up-to-date information about the IUCD. As a result, they base their decisions about whether to provide or use the IUCD on myths and misconceptions about the method, rather than on the latest scientific evidence. A review of obstetric textbooks published in the United Kingdom and United States concluded that the disadvantages of the IUCD tend to be exaggerated, while the advantages are often understated ***(Espey and Ogbourn, 2002)***. In another study, similar misinformation was found in about half of consumer-oriented websites ***(Weiss and Moore, 2003)***. The labeling on some IUCD packages also helps perpetuate under-use of the IUCD by suggesting overly restrictive criteria for who can use the method ***(ARHP, 2004).***

Results of recent studies, however, confirm that the IUCD is a safe and extremely effective contraceptive method that is appropriate for use by most women including those who are under 20 years of age, are nulliparous or nulligravid, are HIV-infected or have AIDS but are clinically well and on antiretroviral (ARV) therapy, or have a history of pelvic inflammatory disease (PID) or ectopic pregnancy. The studies also establish the

negligibility of associated risks. This growing body of evidence has led to important changes in the WHO medical eligibility criteria (MEC) for contraceptive use, which suggest that the advantages of IUCD use generally outweigh the risks for most women, even in the presence of many conditions previously thought to be precautions or contraindications to IUCD use . Thus, the IUCD is re-emerging as an excellent choice for most women seeking long-term, reversible contraceptive protection. ***(WHO, 2004)***

Basic Information about the IUCD

Types of IUCDs

Common types of IUCDs available worldwide are as follows:

- Copper-bearing, which includes the Copper T 380A (TCu 380A, TCu 380A with Safe Load; and TCu 200C), the Multiload (MLCu250 and Cu375), and the Nova T
- Medicated with a steroid hormone, such as Mirena®, the levonorgestrel-releasing intrauterine system (LNG-IUS)

The Copper T 380A

The main IUCD is the Copper T 380A (or Copper T), which is:

- Widely used.
- Well known for its effectiveness, ease of insertion and removal, wide margin of safety, acceptability to clients, and low cost.
- Effective for at least 12 years.

The Copper T 380A looks like the letter "T" and contains barium sulfate so that it can be seen via X-ray. As shown in Figure 1, there are small copper bands on each "arm" of the T, which ensure that copper is released high in the fundus of the uterus (Figure 2). The "stem" is also wound with copper wire. A thin polyethylene string is attached to the bottom of the stem for easy removal.

Figure (1): Copper T 380A IUCD

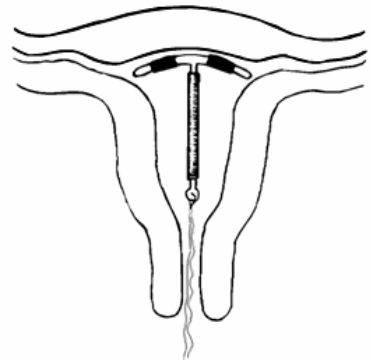

Figure (2): Copper T 380A IUCD inside the Uterus

Source: The Population Council and the Program for Appropriate Technology in Health (PATH) 1989.

Mechanism of Action:

Copper-bearing IUCDs, such as the Copper T, act primarily by preventing fertilization. Copper ions decrease sperm motility and function by altering the uterine and tubal fluid environment, thus preventing sperm from reaching the fallopian tube and fertilizing the egg. ***(Rivera et al., 1999)***

Effectiveness

The IUCD is a highly effective form of long-term, reversible contraception, with an associated failure (pregnancy) rate of less than 1% (0.8%) in the first year of use ***(Trussell, 2004a)***. In a long-term, international study sponsored by the WHO, the average annual failure rate was 0.4% or less, and the average cumulative failure rate over the course of 12 years was 2.2%, which is comparable to

that of tubal sterilization. Service providers can tell their family planning clients that the IUCD is the most effective, reversible contraceptive currently available. ***(United Nations Development Programme et al., 1997)***

Effective Life

The latest scientific evidence shows that the Copper T 380A is effective for at least 12 years, although the US Food and Drug Administration ***(USFDA)*** has approved it for only 10 years. Clients who have had a Copper T inserted should be advised that it should be replaced or removed 12 years from the date of insertion. ***(United Nations Development Programme et al., 1997)***

Return to Fertility

A woman's fertility returns immediately after an IUCD is removed. This message should be made very clear to clients having an IUCD removed: unless they want to get pregnant, they should have another IUCD inserted immediately after removal (if desired and appropriate) or start another contraceptive method. ***(Andersson et al., 1992; Belhadj et al., 1986)***

Side Effects

A common side effect of copper-bearing IUCDs is menstrual changes. Use of the Copper T has been associated with an increase of up to about 50% in the duration/amount of menstrual bleeding, and this is the most common reason for removal ***(Penney et al., 2004)***. Changes in bleeding patterns, such as spotting/light bleeding (between periods), may also occur in the first few weeks. Finally, some women may experience discomfort or cramping during IUCD insertion and for the next several days ***(Grimes, 2004).***

Cramping/pain and changes in bleeding amount/patterns usually are not harmful for the woman and often subside within the first few months after IUCD insertion. Women should be advised of this common side effect before IUCD insertion, and assessed for and counseled about it if needed afterward. Non-steroidal anti-inflammatory drugs (NSAID) can lessen symptoms ***(WHO, 2004b)***, and good counseling can encourage continued use of the method ***(Backman et al., 2002; Zetina-Lozano, 1983)***.

Health Benefits and Potential Health Risks

Non-hormonal IUCDs, such as the Copper T, may protect against endometrial and cervical cancer ***(Hubacher and Grimes, 2002).***

Potential health risks associated with the IUCD, which are uncommon or rare, are discussed below.

- **Uterine perforation**: Perforation of the uterus during IUCD insertion has been shown to be rare, with fewer than 1.5 perforations per 1000 insertions occurring in large clinical trials ***(United Nations Development Programme et al., 1997; Trieman et al., 1995)***. This minimal risk is associated with level of provider skill and experience ***(Harrison-Woolrych et al., 2003)***. When the IUCD is inserted by a skilled provider, the risk has been shown to be as low as 1 per 1000 insertions ***(WHO, 1987)*** and 1 per 770–1600 insertions ***(Nelson, 2000)***. If perforation occurs, the risk of serious complications is low and the need for surgical intervention rare ***(Penney et al., 2004)***.

- **Expulsion**: Although IUCD failure is rare, expulsion is the most common cause ***(ARHP, 2004)***. In the first year of IUCD use, 2–8% of women spontaneously expel their IUCDs ***(Trieman et al., 1995)***. Several factors influence the risk of expulsion, the most important of which is the skill and experience of the provider ***(Chi, 1993)***. Another important factor is timing. Expulsion is most likely to occur within the first 3 months post insertion and is more common in women who are nulliparous,

have severe dysmenorrhea, or have heavy menstrual flow ***(Zhang et al., 1992)***.

The risk of expulsion is higher (11–25% after 12 months of use) when the IUCD is inserted immediately after childbirth (more than 10 minutes but less than 48 hours after delivery of the placenta) ***(Trieman et al., 1995)***, and higher when inserted immediately after a second-trimester abortion ***(Grimes et al., 2002)***. Correct insertion, with the IUCD placed high in the uterine fundus, is thought to reduce the chances of expulsion.

- **Infection:** According to the latest research, the risk of upper genital tract infection among IUCD users is less than 1%, which is much lower than previously thought. This minimal risk is highest within the first 20 days after IUCD insertion, and is thought to be related to insertion technique (due to lack of proper infection prevention practices) rather than to the IUCD itself ***(Hatcher et al., 2004)***. After the first 20 days, the risk of infection among IUCD users appears to be comparable to that among non-IUCD users ***(Hatcher et al., 2004)***.

Common Misconceptions about the IUCD

Many misconceptions about the IUCD remain despite scientific evidence to the contrary. The following section

presents recent research to refute some of these misconceptions, while providing a basis for new recommendations and practices related to intrauterine contraception.

The IUCD Does Not Act As an Abortifacient

Studies suggest that the IUCD prevents pregnancy primarily by preventing fertilization rather than inhibiting implantation of the fertilized egg. This is particularly true of the copper- bearing IUCDs. ***(Rivera et al., 1999; Alvarez et al., 1988; Segal et al., 1985)***

The IUCD does not increase a woman's risk of ectopic pregnancy

The IUCD reduces the risk of ectopic pregnancy by preventing pregnancy. Because IUCDs are so effective at preventing pregnancy, they also offer excellent protection against ectopic pregnancy. Women who use copper-bearing IUCDs are 91% less likely than women using no contraception to have an ectopic pregnancy ***(Sivin, 1991)***.

The following points should also be considered:

- In the unlikely event that an IUCD user does become pregnant, that pregnancy is more likely to be ectopic than is a pregnancy in a nonuser because the IUCD

offers less protection against ectopic than intrauterine pregnancy ***(Nelson, 2000)***.

- Among IUCDs, the Copper T 380A and Multiload Cu375 are lowest in rates of ectopic pregnancy ***(WHO, 1987*)**. A long-term study of women using the Copper T 380A found the rate to be less than 1 (0.09%) per 100 women at 1 year, and less than 1 (0.89%) per 100 women at 10 years ***(Ganacharya et al., 2003).***
- Women with a history of ectopic pregnancy can use the IUCD with no restrictions.

The IUCD does not cause PID, nor does the IUCD need to be removed to treat PID

Strict randomized controlled trials and literature reviews reveal that PID among IUCD users is rare ***(ARHP 2004; Grimes, 2000)***. Early studies that reported a link between PID and IUCD use were flawed and poorly designed. Inappropriate groups were used for comparison, infection in IUCD users was over-diagnosed, and there was a lack of control for confounding factors ***(Buchan et al., 1990; Vessey et al., 1991).***

Here are some important points about PID and the IUCD based on more recent research:

- During the first 3−4 weeks after IUCD insertion, there is a slight increase in the risk of PID among IUCD

users compared to non- IUCD users, **but it is still rare** (less than 7/1000 cases). After that, an IUCD user appears to be no more likely to develop PID than a non-IUCD user ***(Farley et al., 1992)***.

- PID in IUCD users is caused by the STIs gonorrhea and chlamydia, not the IUCD itself ***(Darney, 2001; Grimes, 2000)***. However, the risk is still very low, with an estimated 3 cases per 1000 insertions in settings with a high prevalence (10%) of these STIs ***(Shelton, 2001)***.
- If PID occurs, the infection can be treated while the IUCD is kept in place, if the woman so desires. Studies have shown that removing the IUCD does not have an impact on the clinical course of the infection. If the infection responds to treatment within 72 hours, the IUCD does not need to be removed ***(WHO, 2004b)***.
- Randomized controlled trials and cohort studies reveal that the monofilament string does not increase the risk of PID ***(Grimes, 2000)***.
- Women who have a history of PID can generally use the IUCD (the advantages generally outweigh the risks), provided their current risk for STIs is low.

The IUCD does not cause infertility.

Infertility caused by tubal damage is associated not with IUCD use, but with chlamydia (current infection or— as indicated by the presence of antibodies— past infection) ***(Hubacher et al., 2001)***. Moreover, there is an immediate return to fertility after an IUCD has been removed ***(Belhadj et al., 1986)***. In one study, 100% of women who desired pregnancy (97 of 97) conceived within 39 months of IUCD removal ***(Skjeldestad and Bratt, 1998)***.

The IUCD is suitable for use in nulliparous women.

Nulliparous women can generally use the IUCD (the advantages generally outweigh the risks). In theory, the smaller size of a nulligravid uterus may increase the risk of expulsion, whereas uterine enlargement, even if due to an abortion, may promote successful IUCD use ***(Hatcher et al., 2004)***. Expulsion rates tend to be slightly higher in nulliparous women compared to parous women ***(Grimes, 2004)***.

The IUCD can be safely used by HIV-infected women who are clinically well.

HIV-infected women who are clinically well can generally use the IUCD (the advantages generally outweigh the risks). A large study in Nairobi showed that HIV-