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A SYSTEMATIC REVIEW EVALUATING THE EFFECTS OF BILATERAL TUBAL LIGATION ON MENORRHAGIA AND DYSMENORRHOEA (POST-TUBAL LIGATION SYNDROME)

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Abstract

Introduction: The complaints about the tubal sterilization surgery leading to post-tubal ligation syndrome first surfaced in the 1950s. With the introduction in the 1970s of laparoscopy, which was a less invasive surgery, more women choose tubal ligation as a family planning method, and reports of complaints of tubal-ligation syndrome increased. Changes in menstrual flow, dysmenorrhoea, menorrhagia and change in cycle length after tubal sterilization have been reported in several studies since 1970. The term "post tubal ligation syndrome" has been used to refer to these changes. Often studies have failed to account for the cause in the menstrual changes other than tubal ligation.

Objective: The primary objective of this research project was to evaluate the long-term risks associated with female tubal ligation by executing a systematic review.

Search strategy: An electronic search of available search engines was used to draw literature relevant to bilateral tubal ligation.

Selection criteria

Types of studies: All randomized controlled, quasi-randomized or clinical controlled trials that mention an experimental and comparison group (own controls were allowed), reporting on long-term risks associated with changes in the menstrual cycle after female sterilization were included in the review.

Types of participants: Women in their reproductive years who had a tubal ligation compared to women who did not have a tubal ligation.

Types of intervention: Tubal sterilization (by macro- or micro-surgery, laparotomy, minilaparotomy or laparoscopy).

Types of outcome measures: Outcome measures relevant to post-tubal sterilization long-term risks concentrating on: Dysmenorrhoea, menorrhagia and duration of menstruation period.

Data Analysis: The reviewer extracted the data unto a data collection sheet. Thereafter it was captured onto a computer. Review Manager software program was used for analyses.

Results: The results showed that women who have a tubal ligation have an increased risk to experience dysmenorrhoea and menorrhagia after the procedure. They may also be at risk to experience an increase in the duration of their menstruation period.

Introduction and problem statement

Bilateral tubal ligation (BTL) is one of the most common methods of fertility regulation in the world. Reliance on both male and female sterilization has grown substantially. It is estimated that more than 100 million women have chosen BTL as a method of birth control (Limpaphayom, 1991:501). The use of female sterilization services has even increased in regions where it had been low before, particularly in Sub-Saharan Africa. In nations such as South Africa, Botswana, Cape Verde, Kenya, Mauritius, Namibiaand Swaziland, sterilization prevalence rates are now 5% or higher. The introduction of minilaparotomy services into family planning programs in Sub-Saharan Africa accounts for this increase in use (Ross, Hong & Huber, 1985:12).

Post Tubal Ligation Syndrome

Complaints about tubal sterilization surgery leading to post-tubal ligation syndrome first surfaced in the 1950s. The term "post-tubal ligation syndrome" was coined to describe a variety of symptoms that have been reported to occur after female sterilization. This syndrome is a controversial constellation of symptoms, including pelvic discomfort (dysmenorrhoea), menorrhagia, ovarian cystic changes, changes in sexual behaviour and emotional health, exacerbation of premenstrual symptoms and menstrual disturbances significant enough to lead to further gynaecological surgery, including hysterectomy or tubal reanastomosis. These changes are suggested to occur as a result of disruption of the utero-ovarian blood supply, which result in disturbances of ovulatory function after tubal ligation (Gentile, Kaufman, & Helbig, 1998:180).

Earlier studies show a strong relationship between sterilization and menstrual disorders, but these studies are challenged because of methodological weaknesses. Corson, Levinson, Batzer, and Otis (1981:363) study showed no significant difference in the hormone levels between women who had been sterilized and those who were not, indicating that the ovaries were not damaged by the surgery. Rulin, Davidson, Philliber, Graves, and Cushman (1989: 149) on the other hand reported that the incidence of dysmenorrhoea is significantly more in patients who underwent sterilization.

Previous method of contraception may also contribute to changes in the menstrual cycle post sterilization (Lieberman, Belsey, Gorndon, Wright, Letchworth, Noble, & Niven, 1978:376). Six months after the tubal ligation, women who had previously used oral contraceptives reported a significant increase in days of menstruation, more dysmenorrhea, and an increase in excessive bleeding. Wilcox, Martinez-Schnell, Peterson, Ware and Hughes (1992:1368) controlled for prior contraceptive use, and reported an increase in menstrual pain and bleeding after sterilization. DeStefano Huezo and Peterson (1983:673) reported a decrease in cycle length and days of menstrual bleeding and an increase in pain only when tubal ligation was done by unipolar cautery. While Reidel, Ahrens and Semm (1981:353) reported significantly fewer menstrual complaints when endocoagulation rather than unipolar cautery was used for the sterilization procedure. Shain, Miller, Mitchell, Holden & Rosenthal (1989:192) reported significant menstrual changes and more pain when bipolar cautery or Pomeroy procedure

was used, but not when Falope ring procedure was used. Patis and Cullins (2000:859) deny the claim that changes in the menstrual cycle after two years could still be ascribed to the actual tubal ligation.

The debate on the existence of post-tubal ligation sydrome continues as professionals differ on the existence of such a syndrome. The number of women who claim to have post-tubal ligation syndrome is not known in the medical literature. However the syndrome has been a popular topic in Internet chat rooms and support groups and women worldwide struggle to find answers to their menstrual disturbances after tubal ligation as medical experts refuse to accept that post-tubal ligation syndrome does exist (Bloom, 2004).

It is evident from the literature that post-tubal ligation syndrome does exist. The current problem is the contradictonary information that is in the literature. An extensive literature search could not identify a systematic review on the effects of bilateral tubal ligation on the menstrual cycle. The current available evidence is ambiguous. The current literature is contradictive when reporting on post-tubal sterilization syndrome. Due to the inconclusive literature as to whether tubal ligation causes menorrhagia and dysmenorrhea, the researcher decided to undertake a systemic review on the long-term effects after bilateral tubal ligation so that women can be aware of the long-term complications of female sterilzation.

Research objective

The primary objective of this research project was to evaluate the long-term risks associated with female tubal ligation by executing a systematic review. The research question that arises is: Does bilateral tubal ligation cause long-term risks associated with the menstrual cycle?

Research design and methodology

Types of studies

All randomized controlled, quasi-randomized or clinical controlled trials that used a comparative group or own controls, and that reported on long-term risks associated with changes in the menstrual cycle after female sterilization were evaluated for inclusion in the review.

Types of participants

Women in their reproductive years who requested bilateral tubal ligation as a form of birth control, irrespective of the surgical procedure or the sterilization method. Control groups may consist of women who had partners who were sterilized.

Types of intervention

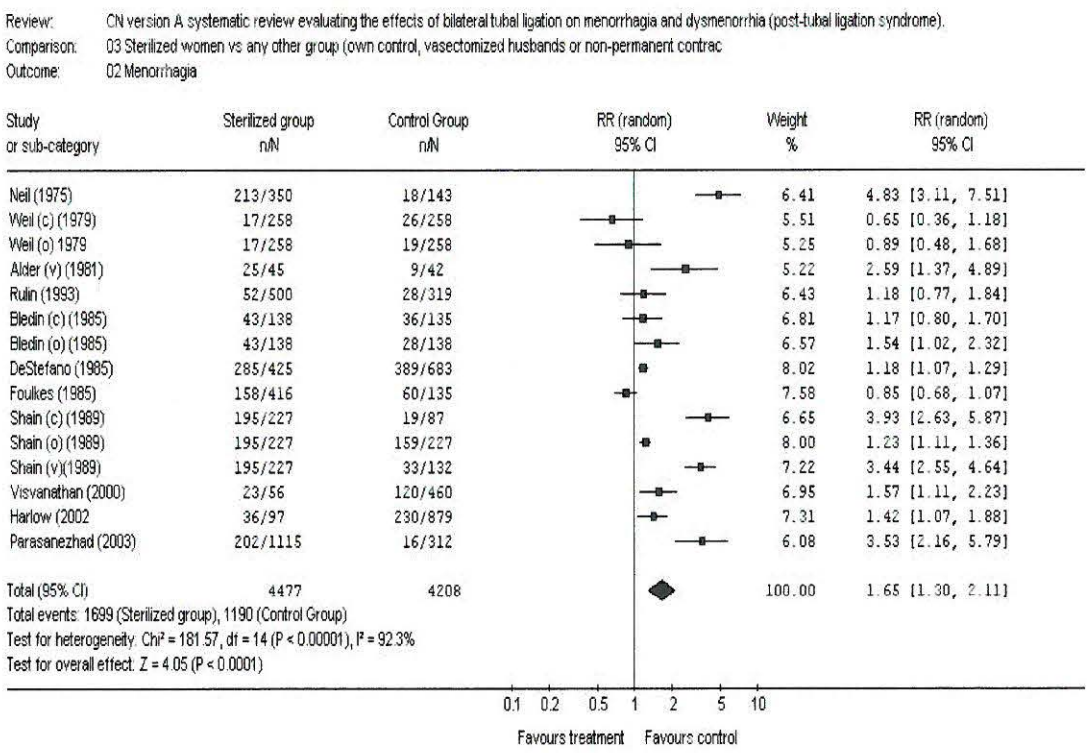
Post-tubal sterilization using any method of surgery (macro- or micro-surgery, laparotomy, minilaparotomy, laparoscopy or culdoscopy) and any method of tubal occlusion (coagulation, rings, clips, sutures and excision).

Types of outcome measures

Studies considered for inclusion in this review were appropriately designed to evaluate the objective outcome measures relevant to post-tubal sterilization long-term risks of:

who used any method of non-permanent contraception, the difference was not statistically significant (NS).

Figure 2. Menorrhagia: Sterilized women vs any other group (own control, vasectomized husbands or non-permanent contraception.



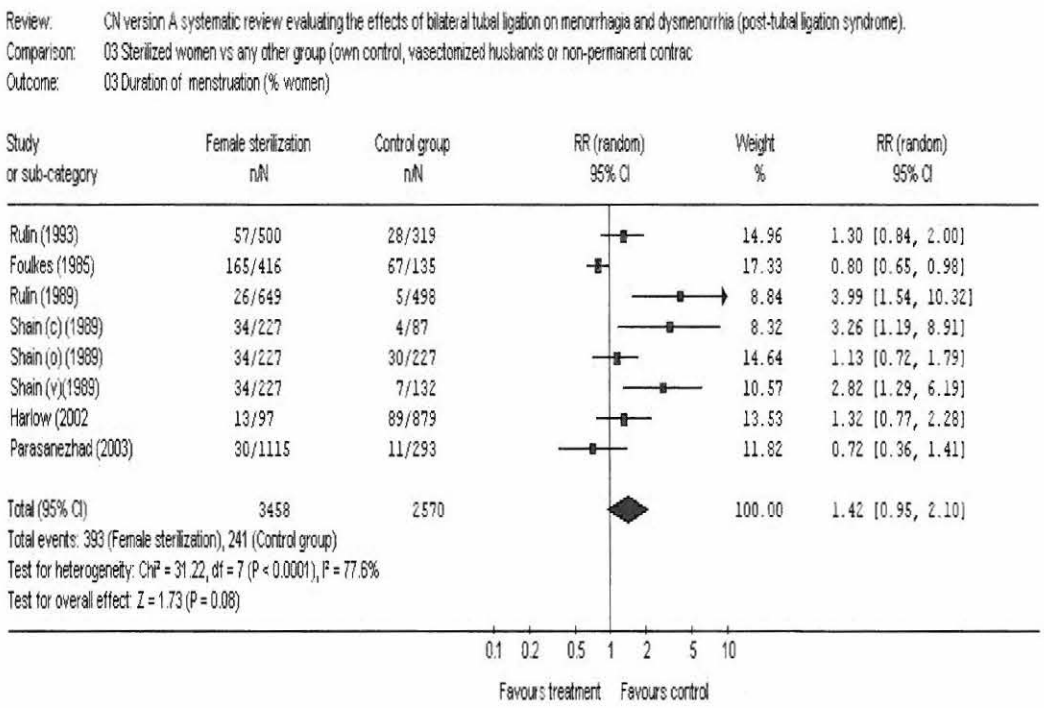
Sterilized women versus any other group (own control, vasectomized husbands or non-permanent contraception (Figure 2) 37.9% (1699 / 4477) vs 28.3% (1190 / 4208) RR 1.65 CI 1.30 – 2.11, P <0.0001. The results above show that sterilized women have an increased risk to experience menorrhagia after tubal ligation. The risk showed a statically significant difference between the comparisons.

3. Increase duration of menstruation

Eight "sub studies" studies were identified that reported on women who experience an increase in the duration of menstruation period.

All four of the comparisons showed a slight increase in the percentage of women who reported that they experienced an increase in the duration of their menstruation period, but none of the results showed a statistical significance.

Figure 3. Increase duration: Sterilized women vs any other group (own control, vasectomized husbands or non-permanent contraception.



Sterilized women versus any other group (own control, vasectomized husbands or non-permanent contraception (Figure 3) 11.4% (393 / 3458) vs 9.4% (241 / 2570) RR 1.42 CI 0.95 – 2.10, P = 0.08. The results above shows a slight increase in the percentage of women who reported an increase in the duration of their menstruation period, but the results are not statistically significant.

Discussion of the results

Systematic reviews recapitulate large amounts of information and are more likely than individual trials to explain the true clinical effect of an intervention. Evidence from clinical research is becoming more and more important in medical-practice decisions as more and better evidence is published. Individual studies that involve only small numbers of patients may have results that are indistinct and may thus lead to less than optimal decisions. The research process of a systematic review is able to identify, critically appraise, and review all the relevant studies on a clinical question and is more likely to give a valid answer. The systematic review uses rigor methods and quality standards to reduce bias. The systematic review results are the closest to reaching the truth given the current state of knowledge when treatments are involved (McQuay & Moore, 1997:712).

The current systematic review findings were compared with the findings of other scientific publications. The results of the current systematic review were consistent throughout,

indicating that symptoms of "post- tubal ligation syndrome" do exist. Meta-analyses have shown that women who had a bilateral tubal ligation experienced a significant increase in dysmenorrhoea and menorrhagia compared to women who have not been sterilized. They may also be at risk to experience an increase in the duration of their menstrual period.

Shy, Stergachis, Grothaus, Wagner, Hecht and Anderson (1992:1698) reported on a study where they compared women who had been sterilized to women whose husbands had vasectomies. They found that 97% of the women who were sterilized and admitted to hospital due to gynaecological reasons complained about menorrhagia and seven percent complained of dysmenorrhoea. Poma (1980:272) also reported an increase in hospitalization of women for abnormal menstrual bleeding after female sterilizations. Punnonen and Erkkola (1984:149) and Buytaert and Viane (1980:119) supported this and noted an increase in menorrhagia after the women had a tubal ligation. Wilcox et al. (1992:927) noted an increase in menstrual pain in women five years after they had a tubal ligation. Studies done by Reidel, Ahrens and Semm (1981:353) compared different sterilization methods and concluded that sterilization done by endocoagulation results in fewer women complaining of menorrhagia than the group who had a sterilization via unipolar technique. Chamberlain and Foulkes (1976:1475) also did a study on different techniques used for sterilization and agree that different sterilization methods yield an increase in both groups regarding menorrhagia and may increase the duration of bleeding period.

In contrast, other authors such as DeStefano et al. (1983:673); Fortney, Cole, Kennedy (1983:831) and Rubinstein Benjamin and Kleinkopf (1979:631) reported that they do not support an increase in dysmenorrhoea and menorrhagia after sterilization as they observed no differences in the women in their studies. Bhiwandiwala, Mumford and Feldblum (1983:685) did a study comparing different techniques of sterilization and they also reported that they found no changes in these characteristics in women before and after the sterilizations. Kasonde and Bonnar (1976:575) and Kwak, Chi, Gardner and Laufe (1980:67) compared women's menstrual cycles before and after sterilizations and reported that they did not find any difference in the menstrual cycle regarding dysmenorrhoea or menorrhagia.

A review of the literature on post-tubal ligation problems by Hargrove and Abraham (1981: 359) revealed an incidence of long-term complications in as many as 22 to 37% of sterilized women. The recent publications, on the other hand, give clearly lower percentages (Rubinstein et al., 1976: 631; Stock, 1978: 173) because the results were adjusted for use of oral contraceptives and pre-existing gynaecological complaints, the incidence has decreased between 5.4 to 6.0%. In the study done by Buytaert and Viaene

(1980: 119) in 322 participants a figure of 7.1% of menorrhagia and six percent for dysmenorrhoea was found in sterilized women. Chamberlain and Foulkes (1976:1475) were the first to report the effect of prior contraceptive use on menstrual symptoms after tubal sterilization. Chamberlain and Foulkes (1976:1544) found a significant increase in both pain and bleeding after sterilization in the 74 women who had been using Intrauterine devices (IUDs).

Implications for practice

The reviewer acknowledged that the conclusions of this review are drawn from poor quality studies with a heterogenous background. Yet, it is recognized that the included studies were the best evidence currently available on the issue of post-tubal ligation syndrome. Strict rigor was applied when the included studies were selected, which give some support for the findings of the review. It is evident from the review that health care givers need to inform their clients about the possible increase in dysmenorrhoea and menorrhagia after a tubal ligation. Some women may also experience a slight increase in the duration of their menstruation period. In the light of no other evidence should we at this stage make women aware about possible long-term effects, but the results should not be emphasized and women should not be lead to belief that they should not opt for a tubal ligation. The important lesson is not that women should avoid tubal sterilization because of the probability of increased menstrual problems, rather that they should be aware of all the risks before tubal ligation, as well as to consider the benefits of tubal ligation as a contraceptive method. Any change can be upsetting, but if a woman is prepared for the likelihood of change, it becomes easier to adjust to and accept the change.

The reviewers recommendations

- Adequate counseling before a tubal sterilization is a must. It is important that the women make an informed choice.
- The immediate risks and the probable long-term risks should be made known to the women before the sterilization procedure.
- A complete investigation for any gynaecological problems must be done before the sterilization surgery. This is to ascertain any conditions that can cause menstrual disturbances post tubal sterilization. A hysterectomy may also be advisable if medical conditions exist, that may put the women at a high risk.

- Previous users of hormonal contraceptives and intrauterine devices should be made aware of the withdrawal effects of the method of contraceptive before the sterilization procedure.

Implication for future research

The aim of this review was to establish the long-term effects of tubal ligation on the specific parameters of the menstruation pattern vs post-tubal ligation syndrome. It

is highly evident that there is a lot of literature on this topic. The problem is that not one study was found that included a well-controlled comparative group of women. Most of the studies were sub-analysis of other primary trials. There were huge differences in the sample sizes of the comparative groups. A large number of the studies were retrospective trials, which recall on memory for the information that was included in the data analyses.

As stated before, this intervention does not lead to the possibility of a randomized controlled trial, but it does not exclude primary research using well-controlled comparative groups. The researcher recommends that health care workers should embark on prospective trials that include well-controlled comparative groups. The inclusion criteria could be well described to ensure that the groups are similar before the intervention. For example a good study would use women whose husbands requests vasectomies. The groups could then be match for many variables before inclusion in the trial. Inclusion criteria could be: age, education, parity, race, similar previous contraceptives, both groups will not use any contraception before the interventions etc. The interventions could then be executed during the similar time periods. The outcome data can then be prospectively collected after the interventions have occurred.

Conclusion

It is evident from this review that bilateral tubal ligation may have long-term effects that may influence the menstrual cycle. Clinicians must no longer decline the existence of "post-tubal ligation syndrome", but should rather acknowledge the possible changes that may occur in the menstrual cycle after sterilization. Women should be made aware that they might experience an increase in dysmenrrhoea, menorrhagia and an increase in the duration of the menstruation period after a bilateral tubal ligation. Primary researchers should be encouraged to embark only on well-controlled comparative studies to enhance the quality of the outcomes.

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