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Short communication

Assessment of menstrual blood loss in Belgian users of the frameless copper-releasing IUD with copper surface area of 200 mm^2 and users of a copper-levonorgestrel-releasing intrauterine system

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Abstract

Objective: This study was conducted to evaluate the effect of a miniaturized frameless copper IUD (GyneFix® 200 small) and a copper-levonorgestrel (GynePlant™) intrauterine system (IUS) on the amount of menstrual blood loss (MBL).
Methods: In 60 Belgian women using GyneFix 200 and 21 using GynePlant, MBL was assessed with the visual assessment technique.
Results: MBL scores in GyneFix 200 users did not change from baseline during the mean observation period of 31 months. In GynePlant users, mean MBL scores decreased by at least 50% in all but one user.
Conclusion: The impact of copper IUDs on MBL can be minimized by reducing the surface area of the foreign body. Reduction of MBL, without causing amenorrhea, can be obtained by adding levonorgestrel.

Keywords: GyneFix copper contraceptive; Anchored IUS; Frameless IUD; GynePlant

1. Introduction

The standard GyneFix® with effective copper surface area of 330 mm^2 is a highly effective intrauterine contraceptive device (IUD). Cumulative failure rates range from 0.0/100 users to 2.5/100 users up to 10 years of use (data from published and unpublished randomized and nonrandomized comparative clinical trials) [1]. The high efficacy of the GyneFix IUD is attributed to the fact that the frameless device is anchored to the fundus of the uterus, eliminating downward displacement, which increases the failure rate, and because the total surface area of the copper sleeves (inner and outer surfaces) is available for release of copper ions.

An important drawback of IUDs is their tendency to cause heavy, sometimes painful, menstrual bleeding. Heavy bleeding is the most common cause for IUD discontinuation. The GyneFix standard also increases menstrual blood loss (MBL), although to a lesser degree than the TCu380A IUD [2]. As the increase in MBL in IUD users is proportional to the size of the IUD, it seemed logical to experiment with copper IUD models that have no plastic frame to limit the size of the foreign body. The present study reports on the MBL observed during use of the small GyneFix 200 IUD, compared with before use. Previous studies demonstrated the high efficacy of the small frameless IUD in a 3-year multicenter study [3].

Furthermore, the knowledge that intrauterine progestin-release drastically reduces MBL prompted the authors to assess the effect of a combined copper-levonorgestrel-releasing IUD on MBL.

2. Materials and methods

The use of the study products was approved by the University of Ghent, Belgium.

2.1. Description of the IUD and IUS

The two intrauterine devices are described briefly below (see Fig. 1). They use the same anchoring system as described previously [4].

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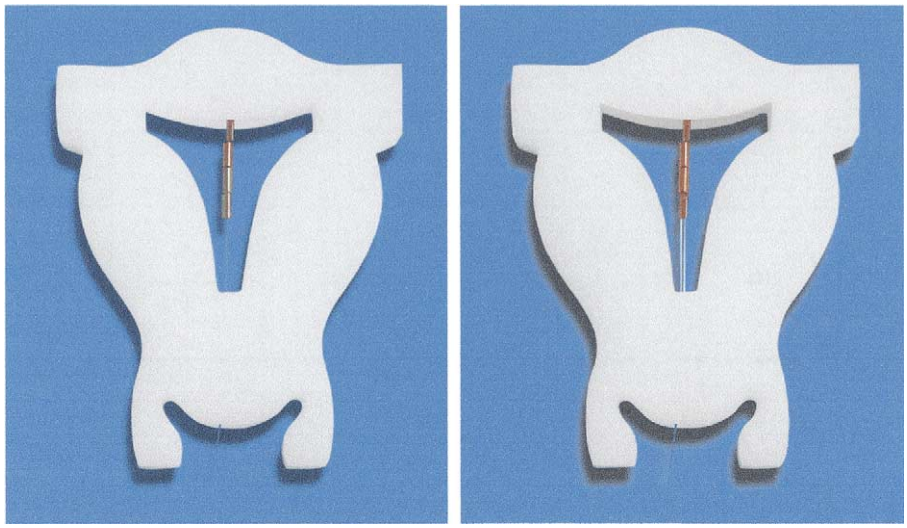

Fig. 1. GyneFix® 200 (small) (left), GynePlant™ (right).

2.1.1. GyneFix 200

The GyneFix 200 (small) IUD consists of four copper sleeves only, with total length of 2 cm, and with total surface area of copper, including the inner and outer surfaces, of approximately 200 mm^2.

2.1.2. GynePlant

The GynePlant IUS consists of the same number of copper sleeves as the GyneFix 200 IUD. Attached to the lower copper tube extends a fibrous delivery system of 1.2 mm in diameter and 1.5 cm in length delivering approximately 5 μg of levonorgestrel (LNG) per day for 3–5 years.

2.2. Assessment of MBL using the visual assessment technique

Women with normal and with heavy menstrual periods were admitted in the study. A visual assessment technique was used as described by Janssen et al. [5]. Information on menstrual bleeding was obtained by interview prior to entering the study using a pictorial chart form to describe the degree to which the sanitary wear was soiled. A score was calculated by multiplying the number of slightly, moderately and heavily soiled pads and tampons by 1, 5 and 20 for pads and 1, 5 and 10 for tampons, respectively, according to their degree of staining (Fig. 2). The visual assessment technique does not yield an exact flow in milliliters but, in practice, the sensitivity and specificity is reasonably high and superior to a woman's subjective assessment of MBL. For purposes of evaluating the effect of treatment, the visual assessment technique is highly practical compared with the quantitative method as women no longer have to carry used sanitary wear to the laboratory.

2.3. Statistical methods

The statistical significance in the studies using the visual assessment technique was calculated according to the Wilcoxon signed-rank test, $p < 0.05$ denoting significance.

3. Results

3.1. GyneFix 200

MBL was assessed in 60 Belgian parous (n = 23) and nulliparous women (n = 37) using the visual assessment scoring technique as described. The trial covers a period from a minimum of 9 months to more than 3 years. Women subjectively reported similar menstruation patterns with the GyneFix 200 IUD when compared with MBL before insertion. This corresponds closely with the menstrual scores (Table 1). The median bleeding score before treatment was 110.5 (range, 28–265) and 110 (range, 28–260) after 3–51 months follow-up, which is not statistically different (p = 0.596).

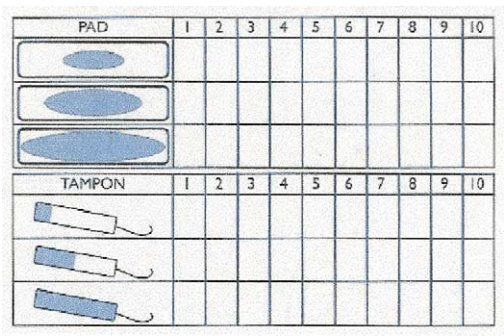

Fig. 2. The pictorial chart form. The numbers 1–8 represent the consecutive days of a bleeding episode.

Table 1
Characteristics of the study group[a] and analysis of the visual menstrual bleeding scores (MS) before and after use of the GyneFix® 200 IUD

	Age	MS at insertion	MS at last follow-up
Mean	30.4	116.7	115.2
SD	8.5	52.9	51.1
Median	30.5	110.5	110.0
IQR	21.3–38.0	80.5–142.0	85.0–137.8
Range	17–46	28–265	28–260

Wilcoxon matched-pair signed-rank test: p = 0.596 (NS).
[a] N = 60, parous n = 23, nulliparous n = 37.

3.2. GynePlant

MBL was assessed in 21 Belgian parous (n = 7) and nulliparous women (n = 14) using the visual assessment scoring technique. The trial period ranged from 8 months to more than 2 years. All women reported reduced bleeding except one. In the latter, menstrual bleeding remained the same as before. No cases of amenorrhea (absence of menstrual bleeding during a period of 3 months) resulting from endometrial suppression were encountered (Table 2). The mean bleeding score before treatment was 222.6 (range, 40–530) and dropped to a mean score of 64.4 (range, 5–150) after 8–28 months follow-up, which is highly statistically significant ($p < 0.001$).

4. Discussion

This article evaluated ways to minimize the effect on MBL and to reduce the amount of menstrual bleeding with copper-releasing IUDs. Although the mechanism by which this occurs is complex, the remedy seems to be simple. The present studies suggest that by significantly reducing the surface area of the foreign body, the impact on the amount of menstrual bleeding will be minimized. A previous MBL study found that the frameless copper-releasing IUD has less impact on MBL than the larger TCu380A IUD [2]. The frameless IUD may also reduce prolonged or intermenstrual bleeding due to the absence of a frame, eliminating the risk of endometrial trauma. Reducing the copper surface area, however, does not affect MBL. Milson et al. [6] showed that women using MLCu250 do not have reduced MBL compared to women wearing a high-load MLCu375 IUD [6]. Further reduction of MBL can be achieved by adding a hormone-releasing system. Levonorgestrel has been extensively studied in this respect. The advantage of GynePlant is that the efficacy of the device is not dependent on the LNG release as its 200 mm^2 of copper surface area exposed to the uterine environment provides high contraceptive protection similar to the high copper-load conventional IUDs, which have a much lower proportion of exposed copper surface area [3,7].

Table 2
Visual menstrual bleeding scores (MS) before and during treatment (observation from 8 months to 24 months) in 21 GynePlant™ users

	MS at insertion	MS at last follow-up
n = 21		
Median	170.0	65.0
SD	148.1	39.2
Minimum	40	5
Maximum	530	150

Wilcoxon matched-pair signed-rank test: $p < 0.001$ (highly significant).

A considerable reduction in MBL was seen in all but one woman treated with the "low-dose" (5 μg/d) GynePlant copper-releasing IUS. The development of the frameless device is a response to the growing need to develop high-performing, long-acting, reversible and acceptable contraceptives with a high continuation of use. The GynePlant is a further development that may offer additional advantages, particularly with respect to reduced bleeding. This device could be useful in women with heavy menstruation and who do not accept the amenorrhea associated in many cases with the levonorgestrel intrauterine system. Another advantage of the GynePlant is that the contraceptive efficacy should be maintained after the drug reservoir is exhausted.

5. Conclusion

The impact on MBL with copper IUDs can be minimized by reducing the surface area of the foreign body. Reduction of MBL, without causing amenorrhea, can be obtained by adding levonorgestrel. The small frameless GyneFix IUD minimizes the impact on MBL. It would appear likely that the contraceptive efficacy of the GynePlant will even be enhanced due to the effect of the added potent contraceptive hormone.

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