Intra Caesarean Fixation of Frameless Copper IUD (GyneFix- CS 300)

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Abstract: Background: Postpartum intrauterine device (PPIUCD) can promote the health of the women and children by preventing financial, psychological, obstetric, and other health-related complications associated with closely spaced pregnancies. **Aim of the Work:** to demonstrate the feasibility to anchor a contraceptive device (GyneFix CS 300) in the fundus of the uterus during Cesarean section and compare the expulsion rate between GyneFix CS 300 and copper T-380A. **Patient and Methods:** This study was conducted on 30 healthy women between the age of 20 and 35 years of age scheduled for elective Cesarean section, they were selected from patients attending Ain Shams University Maternity Hospital Cairo Egypt. They were compared with 30 women for whom copperT-380A was inserted at the uterine fundus during cesarean section. **Results:** The expulsion rate is statistically different between the two groups being less in GyneFix CS 300 [p=0.038]. **Conclusion:** The frameless anchored intrauterine IUD is effective in minimizing displacement and expulsion. The results of this study suggest that the Gyn-CS IUD is appropriate for wider intracesarean use.

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1. Introduction

Postpartum family planning is a prevention of unintended and closely spaced pregnancies in the first 12 months after delivery **(WHO, 2013).** During the postpartum period, there is a high chance of having unplanned pregnancy which has an adverse outcome like abortion, premature labor, postpartum hemorrhage, low birth weight baby, fetal loss and maternal death **(Hounton et al., 2015).**

Advantages of immediate postpartum insertion of an IUD include convenience, safety, client motivation, facilitation of proper birth spacing, noninterference with lactation, immediate reversibility, and no requirement for repeated healthcare visits for refills. PPIUD insertion gives women the additional advantage of leaving hospital with long- term contraception after institutional delivery, decreasing the costs borne by patients and the government. It is estimated that at least one- third of births in the UK are not intended at conception **(Lakha et al., 2006).**

PPIUCD can promote the health of the women and children by preventing financial, psychological, obstetric, and other health-related complications associated with closely spaced pregnancies **(WHO, 2013).**

The insertion of immediate PPIUCD is easy and safe when compared with delayed postpartum and interval insertion of the intrauterine contraceptive device (IUCD) **(Canning et al., 2016)** and it can be initiated by a mid-level skilled birth attendant **(Huffling et al., 2008).**

The uterine anchoring of a frameless copper IUD for intra-caesarean insertion using a dissolvable polymeric cap was explored approximately 10 years ago. A clinical trial conducted in China found the use of an anchored/implantable IUD as a means of device retention in women undergoing caesarean delivery to be a valid concept **(Zhang et al., 2004).**

Unfortunately, in cases where removal was necessary due to adverse effects or infection, despite optimal anchoring the device was difficult to remove in the first 2–3 months due to incomplete cap absorption. Recently, modifications were made to the anchoring approach and the insertion applicator to enable both proper intra-caesarean implantation and easy removal of the device. This paper reports on the clinical experience with the frameless GyneFix Caesarean Section -300 (Gyn-CSVR) device ***(Wildemeersch, 2014)*** (Contrel Research, Ghent, Belgium) in a group of 30 women undergoing caesarean delivery. Previous pilot and randomised trials have demonstrated the high effectiveness of this novel device, specifically developed for intraoperative caesarean section insertion, to prevent displacement and expulsion **(Unal et al., 2018).**

Aim of the Work:-

The primary objective of this study was to demonstrate the feasibility to anchor a contraceptive device (GyneFix CS 300) in the fundus of the uterus

during Cesarean section and compare the expulsion rate between GyneFix CS 300 and copper T-380A.

2. Subject & Method:-

The study group included 30 healthy women between the age of 20 and 38 years of age scheduled for elective Cesarean section, they were selected from patients attending Ain Shams University Maternity Hospital Cairo Egypt.

This was compared with 30 women for whom copperT-380A was inserted manually at the uterine fundus during cesarean section.

All participants were enrolled in the study if they met the inclusion criteria, if they had an intact and anatomical uterus and were able to make a follow-up visit at 6 weeks and again at 3 months. Women with a known anomaly of the uterus (fundal fibroid or congenital anomaly) were excluded from the study and other exclusion criteria like presence of infection of the uterus, history of irregular cycles, blood clotting disorders and undiagnosed genital genital tract bleeding, any cardiac, renal or hepatic disease.

The study was explained to all participants along with potential benefits of the method and possible risks.

The study was approved by Ethics Committee of AIN SHAMS UNIVERSITY, CAIRO, Egypt with informed consent being obtained from all participants.

Description of the GyneFix® CS IUD (Wildemeersch et al., 2014).:

The frameless GyneFix Cesarean Section (Gyn-CS®) IUD (Contrel Research, Ghent, Belgium), with visualized anchor, is similar in design to the original GyneFix differing in the distance between the anchoring knot and the first copper cylinder and a modified inserter designed to facilitate implantation following cesarean delivery.

The extended distance is required to compensate for the greater thickness of uterine fundus encountered during pregnancy prior to complete uterine involution which typically occurs approximately 2 months post-delivery. The uterine IUD contains 5 copper cylinders with a total weight of the copper of 350 mg and the effective copper surface area is ~300 mm 2, and is intended to provide long-term non-hormonal contraception. Immediately below the anchoring knot a thin stainless-steel marker, 2 mm long and 0.5 mm wide, is added to allow for verification of the positioning of the IUD via ultrasonic means at both insertion and subsequent follow-up. The approved contraceptive lifespan of the IUD is 5 years comparable with that of the original GyneFix IUD. The Gyn-CS IUD is preloaded onto a specially designed inserter adapted with a modified safety tip which precludes its use in any other conditions other than after cesarean delivery.

Insertion of the GyneFix® CS IUD *(Wildemeersch, 2014).*

Immediately following cesarean delivery and manual removal of the placenta, while bleeding is controlled, the uterus was lifted out of the abdominal cavity. Prior to insertion, the cavity was manually inspected for abnormalities precluding proper placement of the intrauterine IUD. The applicator was then inserted through the surgical incision up to the fundus in the midline. The broad applicator tip was easily palpated through the exterior fundal wall to determine positioning, without any risk of penetration or perforation of the fundal wall. The stylet carrying the IUD was then pushed forward until it became visible on the exterior surface to the uterus. The applicator was then removed, and forceps placed on the tail of the IUD. The noose of the anchoring system was then threaded with a biodegradable suture material such as Vicryl® 3-0 suture (Ethicon, Somerville, NJ, USA) or a generic equivalent. The threaded anchor was then retracted one millimeter below the serosa by exerting traction on the tail of the IUD. The passage of the anchor through the denser serosa layers was clearly felt. One end of the Vicryl absorbable suture was then secured to the serosa and knotted with its other end. The purpose of the Vicryl suture was to ensure retention while involution of the uterus occurs. Once uterine tone is returned to normal after several weeks, the Vicryl suture dissolves and retention is identical to that seen with the conventional anchored device. Finally, the tail was passed through the cervical canal and trimmed. The entire procedure takes approximately 3 to 4 minutes to perform. The Gyn-CS device as well as the applicator are currently CE-marked and approved for use as a long-term contraceptive system throughout the European Union.

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent-samples t-test of significance was used when comparing between two means.
- Chi-square (x^2) test of significance was used in order to compare proportions between qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:
- Probability (P-value)

– P-value <0.05 was considered significant.

– P-value <0.001 was considered as highly significant.

– P-value >0.05 was considered insignificant.

3. Results

The study group consisted of 60 subjects, 30 with a frameless GyneFix-CS 300 IUD and 30 with the copper T380A IUD. The trial strated in February 2018 and ended in December 2018. The primary outcome measure was device expulsion. All women were questioned to participate in the study and were screened according to the eligibility criteria. All cesarean sections were elective sections and women signed an informed consent form before they were enrolled into the study.

The age and parity of the 60 women in this analysis as well as their obstetrical history and other characteristics is shown in table 1. The baseline characteristics are equivalent in each group. All women have a similar mean age and age range, came from low and middle economic classes, have relatively high education and are living in Cairo, Egypt. Median age in the GyneFix - CS group is 30 years (22-40), non of them was primiparous, all having previous c-sectionsexept 2 cases, and 1 case only having vaginal birth after c-section. Median age in the copper T 380A group is also 30 years (22-38), only 1 case was primigravidanullipara, the remaining having previous c-section and 1 case only havig vaginal birth after c-section.

The median duration of follow -up for women in the GyneFix CS group (1st group) was100 days, while that for women in the Copper T 380 A group (2nd group) was 90 days.

There were 2 cases in the GyneFix CS group who lost follow up as the last follow up for them was after 6 weeks, while there were 3 cases in the other group (copperT380A) which lost follow up, two of them had no follow up and one case had last follow up at 6 weeks visit.

All insertions were successful. At the 3-month visit post insertion there was only 1 case of expulsion (3.3%) in group 1(GyneFix CS300 GROUP), whicoccured approximately after 6 weeks post insertion. Puerperium was considered normal and excessive bleeding didn't occur. Apart from the expulsion case, there were no spontaneous expulsions during follow-up with the GyneFix IUD. No pregnancies occured and the device was well tolerated. The anchor marker was visible in the fundus of the uterus on ultrasound in all cases at the last follow-up.

In the copper T380A IUD group, there were totally 6 cases of expulsion (20%) occurred at various times during the 3-month follow-up, 2 of them were before the 6- weeks visit and the other 4 expulsions were after 6 weeks. This was confirmed by ultrasound examination, where the remaining IUDS were in place at the 3-month follow-up visit.

There were a total of 2 cases of removal in the GyneFix CS 300 IUD group (GROUP 1), one for pain which was done at the 6-week follow up visit and the other at the 3-month follow-up visit for PID. In the second group (CopperT380A IUD GROUP), there were a total of 5 cases of removal, 2 of them were for bleeding. The removal was done at the 6-week follow-up visit. Another 2 removals were for pain and also the removal was done at the 6-week follow-up visit, while the last one was for PID and was done at the 3-month follow-up visit.

The tail of GyneFix CS300 was visible in the vagina in the 27 cases. CopperT380 A threads were visible in all cases who continued follow-up.

For the technique of insertion of GyneFix CS 300, the progress in the learning of the insertion was directly related to the time and the number of cases inserted.

The time needed for fixation of GyneFix CS 300 decreased overtime.

The main duration of fixation of IUD was 14 minutes for the first 10 applications, 8 minutes for the second 10 applications, and only 4-3 minutes for the last 10 cases.

So the method is suitable for general obstetrical use and that only limited training is required.

Table (1): Comparison between groups according to expulsion rate.

Expulsion rate	Group I *(n=28)*	Group II *(n=27)*	x2	p-value
Insertion				
Non	28 (100.0%)	27 (100.0%)	0.000	1.000
Yes	0 (0.0%)	0 (0.0%)		
After 45 days				
Non	27 (96.4%)	25 (92.6%)	0.001	0.974
Yes	1 (3.6%)	2 (7.4%)		
Last follow up				
Non	27/27 (100.0%)	21/25 (84.0%)	2.698	0.104
Yes	0/27 (0.0%)	4/25 (16.0%)		
Total Expulsion rate				
Non	27 (96.4%)	21 (77.8%)	4.305	0.038*
Yes	1 (3.6%)	6 (22.2%)		

x^2: Chi-square test
*p-value>0.05 NS; *p-value <0.05 S*

This table shows statistically significant difference between the two groups as regards the expulsion rate.

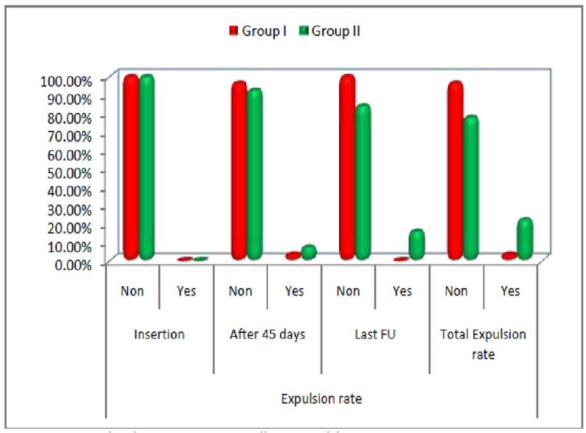

Fig. (1): Bar chart between groups according to expulsion rate.

Fig. 2: Specially designed inserter for Gyn-CS (patent pending), the front end of the inserter is equipped with a triangular tip to be positioned against the fundal wall and serves to prevent perforation with the applicator. Anchoring knot (arrow). Positioned on the tip of the stylet, to securely suspend the IUD to the fundus of the uterus. ***(Wildemeersch, 2014)***

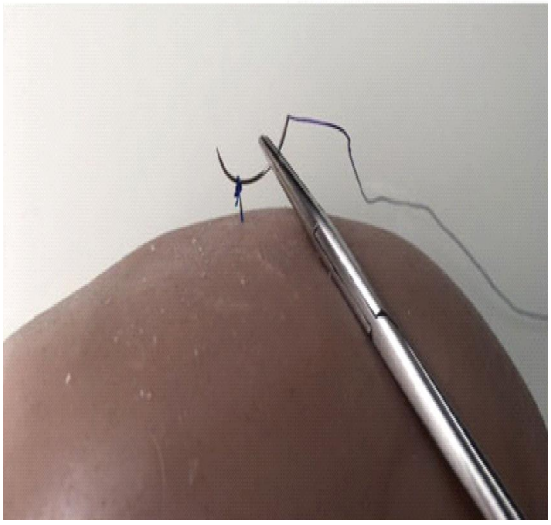

Fig. 3: This figure shows the threading of the biodegradable suture through the noose of the anchoring knot prior to pulling the knot below the serosa ***(Wildemeersch, 2014)***

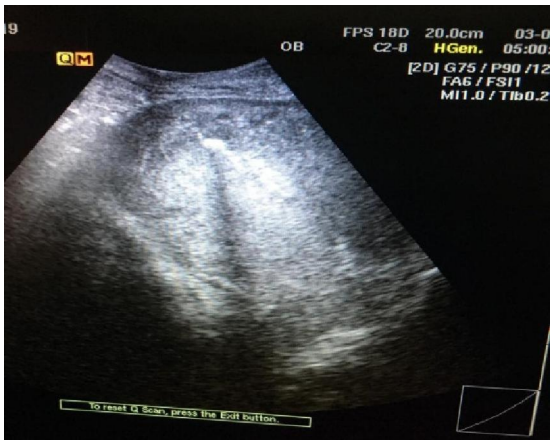

Fig. 4: Before Discharge

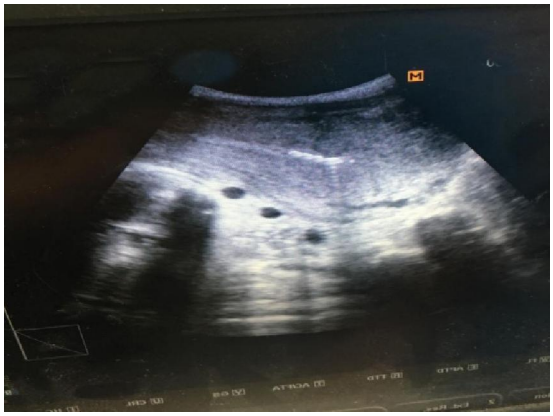

Fig. 5: 6 weeks follow up visit

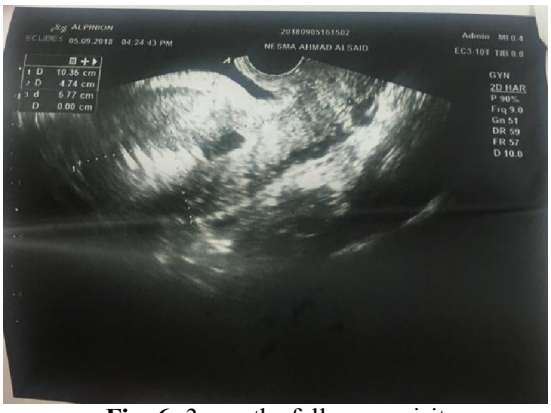

Fig. 6: 3 months follow up visit

4. Discussion:-

Cesarean section rates have been increasing worldwide, and are a growing concern in many countries. Once limited to western countries, particularly the United States and United Kingdom, high rates of cesarean deliveries are now an international phenomenon, reflecting, in part, increased hospital-based delivery and access to healthcare ***(Editorial, 2000)***.

There is a consistent rise in cesarean births in Egypt. **(DOSA,2001)**

The increase in cesarean deliveries in Egypt was not confined to private hospitals. In fact, although cesarean section rates during the 1990s were slightly higher in private hospitals, a considerable increase was also observed in the use of this surgical procedure in public hospital settings.

There are many mechanisms that may have contributed to the increase in cesarean deliveries in Egypt. It is unclear, for example, whether the rise is due to increased complications during delivery, high-risk pregnancies, overuse, patient choice, or other factors. Clearly, recent shifts in the age patterns for fertility in Egypt might be a contributory factor, especially in public hospitals. **(WHO,1985*;* UNICEF, 1997)**

Under certain circumstances, CSs are medically necessary life-saving operations ***(Leeb, 2005).***

However, as with any surgical procedure, CSs have associated risks. Maternal risks of CS include risks of anesthesia, bleeding, infection, incidental trauma to adjacent organs, venous thromboembolism, and even death. Maternal risks in subsequent pregnancies include ectopic implantation, abnormal placentation, including previaand accreta, placental abruption, and uterine rupture ***(Minkoff and Chervenak, 2003; Bergholt et al., 2003; Nielsen and Hokegard 1984).***

Infant risks include those associated with shortened gestation as well as pulmonary and feeding concerns ***(Xie et al., 2015).***

Because of potential risks and sequelae for both mother and infant, CS should only be performed when medically necessary.

Spaced birth is crucial both for the mother and the child's health ***(WHO, 2007; Fotso et al., 2013).***

Birth spacing at least by two years decrease the rate of infant mortality by 50% ***(Conde-Agudelo et al., 2012; Fotso et al., 2013; Dadi, 2015).***

Lactating women are at risk for unwanted or unplanned pregnancy shortly after birth. Moreover, more than 50 % (57.6%) of the women have short birth interval ***(Yohannes et al., 2011).***

Therefore, contraceptive use as early as possible after child birth is important ***(WHO, 2007; Saha and van Soest, 2013).***

The rate of contraceptive utilization is increasing from time to time ***(Hotchkiss and Godha, 2011; Madsen et al., 2014).***

The first postpartum visit is generally scheduled at six-week postpartum ***(Speroff, 2008).*** This visit is either to assess the recovery after childbirth of the mother or to address the needs going forward. Although the postpartum visit is an ideal time to discuss and implement family planning services, there is a notably high default rate from postpartum appointments, particularly among adolescent mothers. This results in delayed or missed counseling opportunities about an appropriate contraception method ***(Moore, 2015 Nkwabong, 2015).***

In addition, nearly half of women are reported to have had unprotected vaginal sexual intercourse before attending a six-week postpartum visit ***(Brito, 2009; Chaovisitsaree, 2012).***

As unintended pregnancy has a negative impact on newborn and maternal health ***(Fraser 1995; Singh 2010; Finer 2011),*** designing effective contraception practices for reducing unintended pregnancy among women who are at heightened risk is of utmost importance.

Provision of contraception usually occurs six weeks postpartum. However, a study conducted in the USA indicated that only 41% of women had a contraceptive received within 90 days after delivery ***(Thiel de Bocanegra, 2013).***

This figure is similar to the reported results from low- and middle-income countries ***(Moore, 2015; Nkwabong 2015).*** Therefore immediate administration of effective contraception is worth consideration. There is an increased risk of unintended pregnancy among women who have delayed initiation of contraception after childbirth or unprotected sexual intercourse before attending a postpartum clinic.

Immediate postpartum provision of highly effective contraception including intrauterine devices (IUDs) and contraceptive implant has been proposed ***(ACOG, 2011).***

Based on a recent Cochrane systematic review, immediate postpartum insertion of IUDs appears to be safe and effective ***(Lopez, 2015).***

Advantages of this practice include high motivation and convenience for both postpartum women and providers. However the expulsion rate of IUDs inserted immediately postpartum is slightly higher than with deferred insertion ***(Lopez, 2015).***

Immediate postpartum insertion of a contraceptive IUD could be a promising choice of contraception. This is quite crucial for postpartum women who are at high risk of missing the six-week postpartum visit, or of having early unprotected intercourse after childbirth, or both.

Intrauterine contraception (IUC) includes the levonorgestrel-releasing intrauterine system (LNG-IUS) and copper-containing intrauterine devices (IUDs).

The LNG-IUS and the CuT 380A IUD provide contraceptive protection similar to that attained with tubal sterilization ***(Trussell, 2011).***

Compared with sterilization, however IUC use is simpler, less expensive, and immediately reversible. IUC use is not very common in 'more developed' regions globally where the most prevalent forms of contraception are condoms and contraceptive pills at 18% each, among women who are married or in union ***(UN, 2011).***

In 'less developed' areas, female sterilization leads at 21% and is followed by IUC use (15%) and contraceptive pills (7%) ***(UN, 2011).*** These statistics are influenced by countries with large populations such as India and China, which are dominated by sterilization and IUC use, respectively. Insertion of IUC immediately after delivery has several advantages. It may avoid the discomfort related to standard insertion and bleeding from insertion will be disguised by lochia. The woman is known to be not pregnant, and her motivation for contraception may be high. For women with limited access to medical care, postpartum care before discharge provides an opportunity to discuss contraception. Delay in initiating contraception is common in the postpartum period because of the challenges of caring for a new infant ***(Teal, 2014a).***

Immediate placement of a long-acting reversible contraceptive, such as IUC or an implant, results in higher use rates. In the USA, however, most insurance reimbursement policies for delivery-related care do not allow separate billing for postpartum IUC or implants prior to discharge ***(Aiken, 2014).***

Women who delay getting IUC may experience an unintended pregnancy or may never return for the insertion ***(Allen, 2009).***

An early study from Colombia showed that 95% of women interested in immediate postpartum IUD insertion had it done. Only 45% of those wishing later insertion ultimately had an IUD inserted.

Another study from Turkey which main objective was to determine the efficacy and safety of immediate TCu 380A IUD insertion during cesarean section after removal of the placenta and measuring the 12-month cumulative rates of pregnancy, IUD expulsion, medically related IUD removal and complications, showed that the 6- and 12-month cumulative rates of expulsion to be 10.6 and 17.6 per 100 women, respectively, with about one third of the subjects having complete expulsion, and in comparing with a previous study including both cesarean (26%) and vaginal (74%) deliveries, TCu 380A model IUD was inserted immediately after the delivery of placenta, and a cumulative 1-year expulsion rate of 12.3 per 100 women was observed ***(Celen et al., 2004).***

The intent of this study (primary outcome measure) is to assess the expulsion rate of a newly developed copper releasing frameless intrauterine IUD GyneFix® Cesarean Section (Gyn-CS®) invented by **DR. Dirk Wildemeersch** (**Ghent University – Belgium**) ***(Wildemeersch et al., 2014).*** At 3 months' follow-up, compared to the TCu-380A IUD, inserted immediately postplacentaldelivery following cesarean section delivery.

This is a pilot study conducted on a limited number of women for the first time in Egypt at Ain Shams University in collaboration with DR. DirkWildemeersch (Ghent University, Belgium) Maternity. The study includes the retention of 60 insertions, 30 Gyn-CS and 30 TCu380A. All women were examined in the first post cesarean section day and ultrasonographic evaluation was done to assess the site of IUD inserted, this was followed by follow-up visits after discharge from hospital at 6 weeks and 3 months.

Insertion of the GyneFix® CS IUD

Immediately following cesarean delivery and manual removal of the placenta, while bleeding is controlled, the uterus was lifted out of the abdominal cavity. Prior to insertion, the cavity was manually inspected for abnormalities precluding proper placement of the intrauterine IUD. The applicator was then inserted through the surgical incision up to the fundus in the midline. The broad applicator tip was easily palpated through the exterior fundal wall to determine positioning, without any risk of penetration or perforation of the fundal wall. The stylet carrying the IUD was then pushed forward until it became visible on the exterior surface to the uterus. The applicator was then removed, and forceps placed on the tail of the IUD. The noose of the anchoring system was then threaded with a biodegradable suture material such as Vicryl® 3-0 suture (Ethicon, Somerville, NJ, USA) or a generic equivalent. The

threaded anchor was then retracted one millimeter below the serosa by exerting traction on the tail of the IUD. The passage of the anchor through the denser serosa layers was clearly felt. One end of the Vicryl absorbable suture was then secured to the serosa and knotted with its other end. The purpose of the Vicryl suture was to ensure retention while involution of the uterus occurs. Once uterine tone is returned to normal after several weeks, the Vicryl suture dissolves and retention is identical to that seen with the conventional anchored device. Finally, the tail was passed through the cervical canal and trimmed.

The direct visualization promotes its simplicity, therefore the method is suitable for general obstetrical use and that only limited training is required.

The results of this postplacental IUD insertion study in cesarean section patients suggest that the implantation technique results in optimal retention of Gyn-CS as there was only one expulsion which upon investigation appeared to be caused by faulty technique (incorrect insertion) or possibly due to inadvertent pulling at the tail during or after the surgical intervention. Despite the reduction in patients enrolled, a statistically significant difference in expulsion rate between Gyn-CS and TCu380 IUD (p=0.038) exists, and that agreed with a similar study occurred in Turkey ***(Unal c et al.,2018).***

Two Gyn-CS devices were removed early in the study, one for pain which was done at the 6-week follow up visit and the other removable device was at the 3-month follow up visit for PID, indicating the possibility of early removal, and that disagreed with the similar study done in Turkey in which there were 2 Gyn-CS devices removed early in the study (2 weeks) presumably before the Vicryl suture was fully dissolved ***(Batar and Wildemeersch, 2004)***.

Due to its frameless design and its fixation to the fundus of the uterus, displacement and embedment of Gyn-CS is avoided. Displacement of conventional T-shape designed IUDs following postpartum insertion occurs frequently. Displacement results in side effects and complications due to embedment of the IUD occurring during or after involution of the uterus ***(Goldthwaite et al., 2016).***

Displacement, embedment or malpositioning of TCu380A in our study is not evaluated. In our study, the tail of Gyn-CS was visible in the vagina in 90% of subjects (in all cases excluding the 2 cases of lost follow-up and the case of expulsion which was not seen at the 3-month follow up visit), while Copper T380 A threads were visible in 70% of subjects (in all cases excluding the 3 cases of lost follow-up visit and the 6 cases of expulsion which occured at various times of follow-up) and that disagreed with the similar study done in Turkey in which the tail of Gyne-CS was visible in the vagina in 58% of subjects and in only 22% of TCu380A subjects ***(Unal c et al., 2018)***, as this study that done in Turkey was on 140 patients including 70 insertions of GyneFix-CS 300 and 70 insertions of CopperT380A.

There was 1 case of removal for PID which possibly could have been prevented by preoperative cleansing of the vagina, not routinely done in the study setting.

Optimal uterine compatibility is more likely to enhance patient continuation rates and overall patient acceptance, as many studies have indicated ***(Goldstuck et al., 2015; Wildemeersch et al., 2016).***

Due to its small size, there is also less impact on menstrual bleeding ***(Wildemeersch and Powe, 2004).***

For these reasons, a frameless IUD or drug eluting-releasing intrauterine system could be preferable for use in the immediate postplacental period.

Precise placement of the anchor, approximately 1 mm below the serosa, is easily accomplished under direct vision. In addition, the position of the anchor marker allows to check its position on follow-up ultrasound examination. Adding more cases would further confirm the safety and validity of the optimized technique and its importance in solving the expulsion and displacement problem of conventional IUDs inserted postplacentally. Furthermore, the anchoring technique and its design is the subject of numerous long-term studies, including removal force studies, showing adequacy of the anchoring concept ***(Wildemeersch et al., 2014)***, and rapid return of fertility following removal of the implanted devices.

For the technique of insertion of GyneFix CS 300, the progress in the learning of the insertion was directly fit with the time and the number of cases. The time needed for fixation of GyneFix CS 300 decreased overtime. The main duration of fixation of IUD was 14 minutes for the first 10 applications, 8 minutes for the second 10 applications, and only 4-3 minutes for the last 10 cases. So the method is suitable for general obstetrical use and that only limited training is required.

There was no training on models prior to fixation of GyneFix CS on patient, this could have diminished the duration of the procedure and is recommended.

Conclusion:

The frameless anchored intrauterine IUD is effective in minimizing displacement and expulsion. The results of this study suggest that the Gyn-CS IUD is appropriate for wider intracesarean use.

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