International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Singh D et al. Int J Reprod Contracept Obstet Gynecol. 2020 Aug;9(8):3381-3387
www.ijrcog.org

pISSN 2320-1770 | eISSN 2320-1789

DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20203327

Original Research Article

Complications after post placental insertion of Cu T 380 A in women undergoing caesarean delivery

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Received: 08 June 2020
Accepted: 08 July 2020

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ABSTRACT

Background: India is the second most populated country in the world after China with more than a billion people and has highest number of maternal deaths in the world. The aim of the study was to find out the complications after insertion of post placental Cu T 380 A in women undergoing caesarean delivery.
Methods: A prospective observational study was carried out in the department of obstetrics and gynecology, Dr RPGMC Kangra (Rural Medical College) after taking approval of Protocol Review and Institutional Ethics Committee of the Institution. A total of 104 women delivering by caesarean section and wanting post-placental intra-caesarean Cu T 380 A insertion and who were meeting WHO standard medical criteria for PPIUCD insertion and were willing to comply with the study protocol was recruited for the study.
Results: There were no major complications and only minor side effects like pain and fever were observed in 6.25 and 6.90 and 9.37 and 11.11% of women who were admitted electively and in emergency, respectively during follow-up visit up to 6 months. String became visible in 72.12% of women at the 6 weeks follow-up visit and their visibilities increased with time and at 6 months follow-up in 90.81% of the cases. Continuation rate was 100% at 6 weeks post-partum follow-up. After that spontaneous expulsion occurred in 4 cases (3.84%) and another 4 women (3.84%) requested removal for various reasons leading to continuation rate of 92.30% at six months post-partum follow-up. There was no case of pregnancy with Cu T in situ with no failure at the end of study at six months post-partum.
Conclusions: Post placental insertion of Cu T 380 A in women undergoing caesarean section was safe and effective method of postpartum family planning, the complaints and complications initially increased but decreased at 6 months follow-up.

Keywords: Elective/emergency admission, Family planning, Intra uterine contraceptive device, Postpartum contraception, Cu-T 380 A

INTRODUCTION

India is the second most populated country in the world after China with more than a billion people and has highest number of maternal deaths in the world. Maternal mortality rate in India is 16.3 while it is only 0.5 in USA.[1] One of the reasons of increased maternal morbidity and mortality is short interval between births due to limited choice of family planning services, fear about side effects of contraceptive method and lack of information. Ensuring healthy timing and spacing of pregnancies is now considered the most important intervention for reproductive, maternal, neonatal, child and adolescent health (RMNCH+A).[2] Indian women have more children than desired and often too closely together.[3] This can be attributed to low level of knowledge, false myths regarding spacing method especially for Cu T and limited medical facilities. Postpartum period is one of the vulnerable periods both for women and infant where health needs of these women as well as the risk of a future unwanted pregnancy should be taken care of. Intra uterine contraceptive device (IUCD) to prevent

pregnancy is among the oldest methods of contraception. The modern IUCD is a highly effective, safe, private, long acting, coitus independent and rapidly reversible method of contraception with fewer side effects. Despite the overall excellent safety profile, side effects and complications can occur at the time of insertion and at different time points following insertion. So, the specific aim of the study was to determine complications that occurred after post placental insertion of Cu T 380 A in women undergoing caesarean section.

METHODS

A prospective observational study was carried out in the department of obstetrics and gynecology, DR RPGMC Kangra at Tanda (Rural Medical College) from August 2016 to July, 2017 on 104 pregnant women, who were admitted to the antenatal/ labour ward with period of gestation 37-42 weeks and delivered by caesarean section and were wanting post-placental intra-caesarean Cu T 380 A insertion. The women who met WHO standard medical criteria for PPIUCD insertion and were willing to comply with the study protocol were recruited for the study.

Inclusion criteria

- Total 18-45 years old, gestational age 37-42 weeks, desire to have CuT after counselling before insertion, no infections, no intra partum haemorrhage and Hb ≥10 gl/dl.

Exclusion criteria

- Women not meeting WHO standard medical eligibility criteria for PP IUCD insertion, known allergy to copper, history of pelvic inflammatory disease, women known to have ruptured membrane for more than 18 hours prior to delivery, women with abnormalities of the uterus, unresolved PPH and HIV/AIDS stage 4 diseases.

Women were counselled about PPIUCD insertion during antenatal visits and/or after admission to the hospital. Women were explained about study in detail including advantage and limitations of methods and repeated counselling was done prior to caesarean section. A written, informed consent was taken from the women who were willing to participate in the study and comply with study protocol. The insertion of IUCD Cu T 380 A was done during caesarean section after delivering the placenta, using the Kelly's forceps/sponge holding forceps/ manually through the uterine incision and fundal placement of the device was ensured. No attempt was made to direct the IUCD strings towards the internal os. Women were observed daily for evidence of postpartum haemorrhage or sepsis and any other complaint during the entire hospital stay. Patients were examined before discharge. The participants were asked to return for scheduled follow-up visits at 6 weeks and 3 months and 6 months. The date of first follow-up visit was mentioned on discharge card and women were reminded telephonically for review on due date. They were asked to report to hospital earlier in case of foul-smelling vaginal discharge different from the usual lochia, lower abdominal pain, fever with chills, suspicion that the IUCD has fallen out, excessive bleeding P/V and feeling of being pregnant.

Statistical analysis

All the observations were recorded in master chart for analysis by statistical package for social science (SPSS) software version (2.0).

RESULTS

Distribution of women according to emergency/elective LSCS

In the present study, more than 2/3rd (72 cases) of patients in whom PPIUCD was inserted, LSCS were done in emergency and only in 32 cases (30.67%) it was done during elective LSCS (Figure 1).

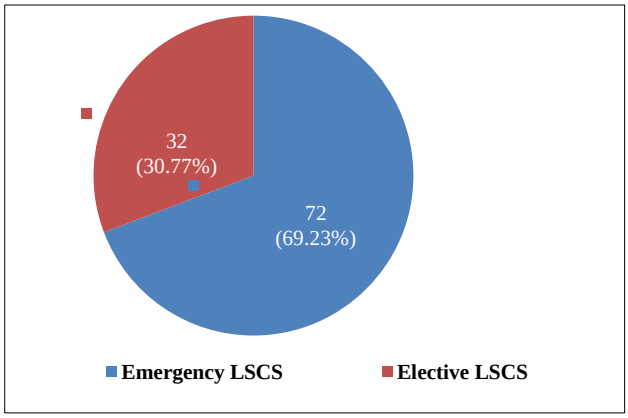

Figure 1: Distribution of women according to emergency/elective LSCS.

Complications during hospital stay

The data in Table 1 reveals that fever and pain were the only complications during the hospital stay of the patients. Pain was recorded in 11 cases (10.58%) while fever was recorded in 7 cases (6.73%). On comparing elective/emergency caesarean section it was found that 2 out of 32 women (6.25%) who had elective caesarean section developed fever while 5 out of 72 women (6.90%) who had emergency caesarean section had fever. Similarly, out of 11 women who had experienced pain in post-operative period, 3 out of 32 women (9.37%) who had elective caesarean section and 8 out of 72 women (11.11%) who had emergency caesarean section complained of pain. Pain was the most common post insertion complication observed in 11 out of 104 women (10.58%) followed by fever in 7 women (6.73%) in this

study. There was no case of PPH, foul smelling lochia, sepsis, wound infection and urinary complications. There was no statistically significant difference in the complications during hospital stay between elective caesarean and emergency caesarean section though the complication rate was slightly higher in the emergency caesarean cases.

Table 1: Post-partum complications during hospital stay.

Complication	Total (N=104)		Elective (N=32)		Emergency (N=72)		p-value	Significance
	No.	(%)	No.	(%)	No.	(%)		
PPH	0	0.00%	0	0.00%	0	0.00%		
Fever	7	6.73%	2	6.25%	5	6.90%	0.90	NS
Pain	11	10.58%	3	9.37%	8	11.11%	0.80	NS
Foul smelling lochia	0	0.00%	0	0.00%	0	0.00%		
Sepsis/post-partum	0	0.00%	0	0.00%	0	0.00%		
Wound infection	0	0.00%	0	0.00%	0	0.00%		
Urinary complications	0	0.00%	0	0.00%	0	0.00%		
Expulsion	0	0.00%	0	0.00%	0	0.00%		

Table 2: First follow-up at 6 weeks of post placental intra-caesarean Cu T 380 A.

Adverse event	Total (N=104)		Elective (N=32)		Emergency (N=72)		p-value	Significance
	No.	(%)	No.	(%)	No.	(%)		
Foul smelling discharge	7	6.73%	2	6.25%	5	6.90%	0.902	NS
Irregular bleeding	6	5.77%	3	9.37%	3	4.16%	0.368	NS
Pelvic pain	14	13.46%	4	12.5%	10	13.88%	0.850	NS
Fever with chills	0	0.00%	0	0.00%	0	0.00%		
Wound infection	0	0.00%	0	0.00%	0	0.00%		
Perforation	0	0.00%	0	0.00%	0	0.00%		
Pregnancy with IUCD in situ	0	0.00%	0	0.00%	0	0.00%		

Table 3: Second follow-up at 3 months of post placental intra-caesarean Cu T 380 A.

Adverse event	Total (N=104)		Elective (N=32)		Emergency (N=72)		p-value	Significance
	No.	(%)	No.	(%)	No.	(%)		
Vaginal discharge	5	4.81%	1	3.13%	4	5.56%	0.590	NS
Irregular spotting	3	2.88%	1	3.12%	2	2.77%	0.920	NS
Excessive bleeding P/V	4	3.85%	1	3.12%	3	4.16%	0.800	NS
Pelvic pain	14	13.46%	3	9.37%	11	15.27%	0.850	NS
Fever with chills	0	0.00%	0	0.00%	0	0.00%		
Wound infection	0	0.00%	0	0.00%	0	0.00%		
Perforation	0	0.00%	0	0.00%	0	0.00%		
Pregnancy with IUCD in situ	0	0.00%	0	0.00%	0	0.00%		

Complications during first follow-up at 6 week of post placental intra-caesarean Cu T 380 A insertion

Common complications recorded at first follow-up visit at 6 weeks of post placental intra-caesarean insertion of Cu T 380 A were foul smelling discharge, irregular bleeding P/V and pelvic pain. Among various complications pelvic pain was the most common complaint reported by 14 cases (13.46%) followed by foul smelling discharge in 7 cases (6.73%) and then by irregular bleeding which was observed in 6 cases (5.77% of women). There was no case of fever with chills, wound infection and pregnancy with IUCD in situ. Though the complication rates were slightly higher in the women who had emergency caesarean section as compared to women who underwent elective LSCS but the difference was not statistically significant (Table 2).

Complications during second follow-up at 3 months of post-placental intra-caesarean Cu T 380 A insertion

During the second follow-up visit at 3 months of post placental intra-caesarean Cu T 380 A insertion it was observed that complications were similar as recorded

during first follow-up visit (Table 3). Pain was the most common complaint during second follow-up visit also which was reported by 14 out of 104 women (13.46%) and 5 (4.81% of women) patients had complaint of discharge per vaginum which was not foul smelling. Seven patients had bleeding complaint at 3rd month follow-up visit out of which 3 patients had irregular spotting on and off and 4 patients had their first menstrual cycle after caesarean section which was excessive. There was no case of fever with chills, wound infection and pregnancy with IUCD in situ. Among 32 women who underwent elective caesarean section 3 women complained of pelvic pain and 1 case each reported vaginal discharge, irregular spotting and excessive bleeding. Among 72 women who underwent emergency caesarean section, 4 women had vaginal discharge, 2 complained of irregular spotting, 3 had excessive bleeding and 11 complained of pelvic pain.

There was no statistically significant difference between elective and emergency caesarean section in the complication rate on 2nd follow-up visit at 3rd month also.

Table 4: Follow-up at 6 months of post placental intra-caesarean Cu T 380 A.

Adverse event	Total (N=98)		Elective (N=31)		Emergency (N=67)		p-value	Significance
	No.	(%)	No.	(%)	No.	(%)		
Vaginal discharge	4	4.08%	1	3.22%	3	4.47%	0.81	NS
Excessive menstrual bleeding	6	6.12%	2	6.45%	4	5.97%	0.67	NS
Pelvic pain	7	7.14%	2	6.45%	5	7.46%	0.85	NS
Fever with chills	0	0.00%	0	0.00%	0	0.00%		
Wound infection	0	0.00%	0	0.00%	0	0.00%		
Pregnancy with IUCD in situ	0	0.00%	0	0.00%	0	0.00%		

Table 5: String visibility with Cu T in situ.

String visibility	Follow-up at 6 weeks (N=104)		Follow-up at 3 months (N=104)		Follow-up at 6 months (N=98)	
	No.	%	No.	%	No.	%
String visible	75	72.12%	86	82.69%	89	90.81%
String not visible	29	27.88%	18	17.31%	9	9.18%

Table 6: USG findings in women where string was not visible on P/S.

Findings	6 weeks (N=29)	3 months (N=18)	6 months (N=9)
In situ Cu T on USG	29	15	8
Cu T expelled	0	3	1

Table 7: Spontaneous expulsion/removal.

Particulars	Hospital stay	1st visit	2nd visit	3rd visit
Expulsion				
a. Partial expulsion	0	0	1	0
b. Complete expulsion	0	0	2	1
Removal	0	0	3	1

Complications during third follow-up visit at 6 months of post-placental intra-caesarean Cu T 380 A insertion

In this study most of the common complications which were noticed in first follow-up visit at 6 weeks and second follow-up visit at 3 months were not recorded during the third follow-up visit at 6 months of post placental intra-caesarean Cu T 380 A insertion (Table 4). Four patients complained of vaginal discharge which was not foul smelling and it was due to vaginal infections like Trichomonas vaginalis and candidiasis. Like previous follow-up visits no case of fever with chills, wound infection and pregnancy with IUCD in situ was observed. During third follow-up visit 7 cases (7.14%) complained pelvic pain and 6 cases (6.12%) had excessive bleeding during menstruation. The complication rate was reduced at 3 follow-ups visit at 6 months. It was noted that there was no statistically significant difference in the complications between the women who underwent elective/emergency caesarean section at the end of study

at 6th month also. In most of studies including the present study pelvic pain and excessive menstrual bleeding were the two most common complaints at 3rd follow-up visit at 6 months.

Visibility of IUCD strings

Data in Table 5 and 6 revealed that Cu T 380 A thread was visible clinically on perspeculam examination in 75 women (72.12%) on first follow-up visit at 6 weeks. Whereas, IUCD strings was not visible in remaining 29 (27.88%) women on the first follow-up visit. In these 29 cases IUCD in situ was confirmed by ultrasound. During second follow-up visit strings became visible further in 11 more cases and strings became visible in total 86 cases (82.69%) as compared to 75 cases (72.12%) during first follow-up visit. In remaining 18 women (17.31%) CuT string was not visible.

In these 18 women USG and X-ray abdomen was done and copper T was found in situ in 15 cases and in 1 case there was partial expulsion into cervical canal which was removed and in 2 cases copper T was not found and had been expelled out. Further 3 more women requested removal of copper T for various reasons. String visibility further increased in the remaining 98 women during third follow-up visit at 6 months and strings became visible in 3 more cases increasing string visibility in 89 out of 98 cases. In the remaining 9 cases (90.81%) string was not visible on third visit. USG and X-ray abdomen was done and Cu T was seen in situ in 8 cases and in one case Cu T had been expelled out.

Table 8: Continuation rate of Cu T 380 A at follow-up (N=104).

Particulars	1st follow-up visit 6 weeks		2nd follow-up visit 3 months		3rd follow-up visit 6 months	
	No.	%	No.	%	No.	%
Continuation	104	100.00%	98	94.23%	96	92.30%
Expulsion/removal	0	0.00%	6	5.77%	8 (6+2)	7.69%
Pregnancy with Cu T in situ	0	0%	0	0%	0	0%

Spontaneous expulsion/removal

During the hospital stay as well as on first follow-up visit at 6 weeks there was no case of expulsion or removal of copper T (Table 7). During 2nd follow-up visit at 3 months spontaneous expulsion of IUCD occurred in 2 (1.92%) cases completely and in 1 case IUCD was partially expelled into cervical canal which was removed. Further 3 more women requested for removal of Cu T 380 A for various reasons leading to 98 women out of 104 with Cu T in situ at the end of 3rd month. During third follow-up visit at 6 months out of 98 women there was one case of complete expulsion of Cu T and in 1 case Cu T was removed on the request of women.

Continuation rate of Cu T 380 A

The continuation rate was 100% up to first follow-up visit at 6 weeks (Table 8). There was a total of 8 cases of expulsion/removal up to 6 months (6 at 3rd month and 2 at 6th month) leading to expulsion/removal rate of 5.77 and 1.92% during second and third follow-up visit respectively. Therefore, at the end of the study at 6 months 94 out of 104 women continued using PPIUCD leading to continuation rate of 92.30%.

Pregnancy with Cu T in situ

In the present study in 104 women who had PPIUCD insertion during the caesarean section, there was no failure as no case of pregnancy with copper T in situ was observed during the follow-up visit up to the end of the study at 6 months postpartum (Table 9).

Table 9: Pregnancy with Cu T in situ.

Follow-up visit	Number of cases with Cu T in situ	Pregnancy
First follow-up visits at 6 weeks	104	0
Second follow-up visit at 3 months	101	0
Third follow-up visit at 6 months	98	0

DISCUSSION

More than 2/3rd of patients in whom PPIUCD was inserted, LSCS were done in emergency. This is because of fact that in study institution nearly 3/4th of LSCS are emergency LSCS. These results are in contrary to that of study by Garuda et al, 4 where they found higher acceptability/insertion during elective LSCS (69.54%).

Pain was the most common post insertion complication observed in 11 out of 104 women followed by fever in 7 women in this study. Whereas in study by Singal et al, and Bedi et al, fever was the most common post insertion complication observed in 2% of the cases each (6/300 and 4/200).[5,6]

Among various complications during first follow-up, pelvic pain was the most common complaint reported by 13.46% followed by foul smelling discharge in 6.73% and then by irregular bleeding which was observed in 5.77% of women. Arshad et al, also reported similar findings.[7] They observed back ache/pain abdomen (14.2%), discharge per vaginal (12.5%) and bleeding (11.6%) to be the common complications during first follow-up visit at 6 weeks. Whereas in the study by Bedi et al, bleeding was the most common complication observed in 17.4% cases followed by pain in 7.6% of cases.[6]

During the second follow-up visit at 3 months pain was the most common complaint during second follow-up visit also which was reported by 14 out of 104 women and 5 patients had complaint of discharge per vaginum which was not foul smelling. These results are in conformity with the findings of Singal et al, and Arshad et al.[5,7] In their study also pain was the most common complaint at 2nd follow-up visit at 3rd month noted in 23.55 and 13.25% of the cases respectively and there was no case of pregnancy with Cu T in situ in their study also.

During the third follow-up visit at 6 months four patients complained of vaginal discharge which was not foul smelling and it was due to vaginal infections like Trichomonas vaginalis and candidiasis. Similarly, the pain was the most common complaint at 6 months follow-up visit in the study by Arshad et al (15%) and Mishra et al (35.60%).[7,8] Whereas excessive bleeding was the most common complaint in the studies by Garuda et al (10.41%), Sharma et al (14.63%), Singh et al (15.70%) and Rahman and Banerjee (6%).[1,4,9,10] However, Vidyarama et al, had observed a very low complication rate of 0.2-0.3% of women.[11] A higher percentage of complications occurred in the studies by Sharma et al, (12-14%) and Singh et al (15.70%).[1,9]

In this study string became visible in 72.12% of women at the 6 weeks follow-up visit and in rest of cases proper placement of Cu-T 380 A was confirmed by USG. The string visibility increased with time and at 6 months follow-up stings became visible in 90.81% of the cases. These results are in accordance with the findings of Zulficar et al, who reported missing thread in 8% of cases.[12] In another study by Garuda et al, missing thread was observed in 14.54% of cases.[4] Comparatively higher percentage of missing thread about 30% and 35.45% was found in studies by Rahman and Banerjee and Shanavas et al, respectively.[10,13] However, Nayak and Jain observed missing thread in only 4.83% of cases.[14]

Similar observations were made by Singal et al, Halder et al, also observed increase in string visibility from 70% at 6 weeks to 79% at 6 months.[5,15] However, Arshad et al, observed only slight increase in string visibility from 94.9% at 6 weeks to 96.4% at 6 months follow-up visit.[7] Whereas, in the study by Zulficar et al, there was no increase in string visibility which was 92% at 6 weeks and similar at 6 months.[12]

Continuation rate was 100% at 6 weeks post-partum follow-up. After that spontaneous expulsion occurred in 4 cases (3.84%) and another 4 women (3.84%) requested removal for various reasons leading to continuation rate of 92.3% at six months post-partum follow-up. Rate of expulsion/removal observed in studies by Gupta et al, Arshad et al, Sharma et al and Bedi et al, was 7.3, 6.2, 9.74 and 5.3% respectively which is similar to the present study.[6,7,9,16] Whereas, more than 2 times higher rate of expulsion/removal was observed by Celen et al, (17.6%), Garuda et al, (16.66%) and Gaikward and Gurram (14.7%) than the present study.[4,17,18] However, Mullar All et al, Vidyarama et al and Shahnavas et al reported a much lower incidence of expulsion/removal of 2.0, 1.2 and 1.8%, respectively.[11,13,19]

There was no case of pregnancy with Cu T in situ with no failure at the end of study at six months post-partum. However, Singal et al, who reported one case (0.63%) of pregnancy with Cu T in situ at 6 months.[5]

CONCLUSION

There are various myths/misconceptions associated with IUCD like infection, perforation, migration and bleeding complications but the present study showed that there were no major complications and only minor side effects were like pain, fever, discharge and irregular bleeding which were observed in only 5-15% of women during hospital stay and during follow-up visit up to 6 months. These side effects were similar to those associated with the normal caesarean section without PPIUCD insertion. In the present study there was no case of perforation. String became visible in 72.12% of women at the 6 weeks follow-up visit and in rest of cases proper placement of Cu-T 380 A was confirmed by USG. The string visibility increased with time and at 6 months follow-up stings became visible in 90.81% of the cases. Continuation rate was 100% at 6 weeks post-partum follow-up. After that spontaneous expulsion occurred in 4 cases (3.84%) and another 4 women (3.84%) requested removal for various reasons leading to continuation rate of 92.3% at six months post-partum follow-up. There was no case of pregnancy with Cu T in situ with no failure at the end of study at six months post-partum. Although the number of women in present study was small, authors conclude that intra caesarean insertion of PPIUCD is practical, convenient, safe, effective and acceptable contraceptive method for spacing of the birth in this rural setting where women have limited access to medical care and chance of women returning for postnatal counselling and contraception is low.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Singh D, Thakur S. Complications after post placental insertion of Cu T 380 A in women undergoing caesarean delivery. Int J Reprod Contracept Obstet Gynecol 2020;9:3381-7.