Original Research Article

A comparative feedback between traditional Copper-T 380 A and Etherena T Cu 380 A a Innovative loading and inserting device to provide a safe and convenient method of IUD insertion

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Abstract

Objectives: To establish comparative results related to insertion of Copper-T 380A using traditional method of insertion versus an innovative inserter (Etherena). Comparison parameters included ease of insertion, fundal placement, time taken to insert, training needs, client comfort and perception during use of different types of Uterine Sound. **Methods:** A comparative single-blinded study was conducted in Muzaffarnagar Medical College, India. One Hundred randomly selected women enrolled between October-2020 and March-2021 for the study. All participants were counselled for family planning, met eligibility criteria, and requested for interval IUD. Resident doctors, with experience in traditional Copper-T insertions prior to study implementation, performed insertions after getting training for Etherena insertion. For traditional Copper-T, metallic uterine soundwhereas a disposable Uterine Sound with Etherena was used. **Results:** Post-insertion ultrasonography showed successful placement of IUD to the fundus in 100% of the cases in both groups.The mean distance from the fundus was 1.82 mm and 3.7mm respectively in Etherena v/s Copper-T group, as assessed by ultrasonography. Mean time taken for the process in both groups was similar (≈90 seconds); it was more consistent in Etherena vs Copper-T. The setting of uterine depth measurement on inserter was easy in 98% vs 88% cases in Etherena v/s Copper-T.Sounding related pain or discomfort was reported in 2% cases of Etherena group vs 48% in Copper-T. Client satisfaction levels reported were 98% for Etherena and 72% for Copper-T. No case of trauma or perforation observed in either group. **Conclusions:** The innovative & safe insertion process using Etherena makes Copper-T 380A insertions more convenient and accessible and significantly comfortable from the client perspective.

Keywords: Traditional Copper-T 380 A, Etherena T Cu 380 A,

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Introduction

India has been expanding range and reach of modern contraceptives since decades and goal is to raise awareness and delivery of quality assured services in rural and urban areas. Among the various methods of contraception the most widely used reversible contraceptive are intrauterine devices (IUD) [1], which is inserted in the uterine cavity. Copper- T 380 A, a T shaped device with a polyethylene frame holding 380mm2 of exposed surface area of copper, is most commonly used.

Uttar Pradesh is the most populous state in India having a MMR of 197 (SRS 2016–2018) which is much above the national average[2]. The Contraceptive prevalence rate in Uttar Pradesh is 45.5% for any method, the unmet need for contraception in Uttar Pradesh is about 7.5% according to Health and Family Welfare statistics in India 2019-20[2].

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In spite of intrauterine devices widelyavailable, only 1.2% current use of IUD/PPIUD among the married women aged 15-49 yrs [3] is reported in as per latest data available for UP. This clearly suggest missed opportunity, more so when more than 75% deliveries taking place in health centres (public and private).The fear, misconceptions and lack of knowledge as well as supply chain and trained manpower to insert IUD shampered IUDs adoption by women. For traditional Copper- T 380 A insertion there are many steps and some of them are very critical steps like manual loading of device in sterile pack, insertion of device by using “no touch technique”, withdrawal technique and followed by second push[4]. It is observed that sometime these steps (anecdotal evidence basis discussion with providers) not done properly like loading of T arms outside sterile pack by gloved hand which may lead to infection or change in step like instead of withdrawal, use push technique which may lead to perforation.

Intrauterine Enablers - Etherena

To make insertion technique simple for health personnel new devicesuch as Intrauterine enablers (IUE) [5] have been introduced with the aim of making the experience of insertion for the provider and users safe, acceptable and comfortable. Device do notrequire manual loading like traditional Copper-T and can be used by two step push and pull process with minimal training. One hand operation by

using IUE with no touch technique provides asepsis during insertion and reduces the chance of infection post procedure. New device work on the principal of withdrawal technique and offers perfect fundal placement. Device has a curve similar to natural uterine curve thus allowing perfect insertion in women with anteverted or retroverted uterus. This comes with a disposable uterine sound which has special rounded top to avoid accidental perforation and it also comes with measures written on sound like metallic sound.

This study aims to provide information on

- Client and provider acceptability, ease of use,
- Client comfort and perception due to use of disposable uterine sound and advanced single handed insertion device
- To establish the comparative results related to fundal placement confirmed by ultrasonography

Materials and Methods

A comparative single blinded study was conducted in Muzaffarnagar Medical College, Uttar Pradesh in India

Muzaffarnagar Medical College was chosen since it is having high case load and all facilities available there. It caters patients not only from the town but from nearby areas. Resident doctors, with significant experience (1.5 yrs to 2.5 yrs) in traditional Copper-T insertions prior to study implementation, performed insertions after getting training for Etherena insertion. An orientation session was conducted for all the providers for Etherena which included demonstration and practice of Etherena insertion on model followed by practice on live case by each provider with at least one client.

A comparative single-blinded study was conducted in Muzaffarnagar Medical College, Uttar Pradesh, India between October-2020 and March-2021. One hundred randomly selected women were enrolled into two groups for the study. Fifty were inserted by using new device Etherena (Copper-T 380 A IUD with Intrauterine enabler)and fifty had insertion of traditional Copper- T 380 A. Women included were married, of reproductive age group, desiring contraception, women after 6 weeks of delivery with no complications in postnatal period, had no chronic illness, metabolic disorder or any gynaecological complaint. Detailed history and Examination was taken. Outcome parameters for evaluation included: type of IUD and uterine sound used, loading of T arms, experience during sounding, measurement of uterine depth on inserter tube, technique of placement, time taken for sounding, loading and insertion of IUD, USG findings to confirm the position of IUD inserted, acceptability and experience of the provider, overall handling of the device and overall satisfaction of women.

Women were counselled and informed about procedure and risks associated. With desire of spacing between pregnancy and use of modern reversible contraception women aged 18– 40 yrs underwent insertion on day 5 of menstrual cycle in outpatient department after taking verbal consent. Women were asked to empty her bladder and placed in lithotomy position. Uterine size and position ascertained by pelvic examination.

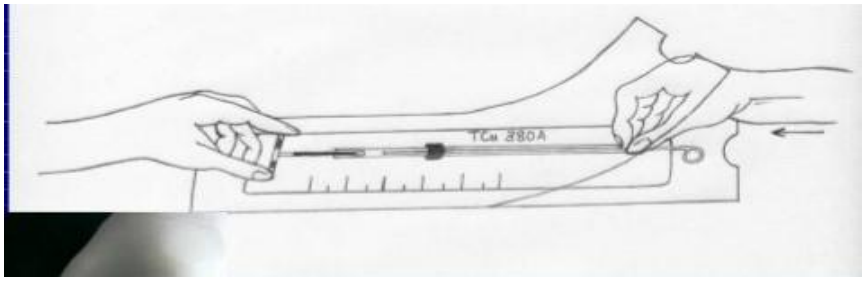

Fig-1: The Insertion technique for traditional Copper-T 380 A involved manual loading of the T arms by no touch technique

Posterior vaginal wall retracted and vagina and cervix cleaned with povidone iodine solution. Anterior lip of cervix held with Allis forceps and metallicuterine sound was introduced to measure the uterocervical length. Blue guardis fixed on the inserter tube of traditional Copper-T 380Abased on uterocervical length and inserted in the uterine cavity with aseptic precautions.

Fig 2: Intrauterine enabler Etherena device

Intrauterine enabler Etherena device has preloaded T of Copper-T 380 A it makes the insertion procedure easier by 2 step push and pull process. Posterior vaginal wall retracted and vagina and cervix cleaned with povidone iodine solution. Anterior lip of cervix held with Allis forceps and ESA (sterile disposable uterine sound) is used to measure the uterocervical length similar to the metallic sound. The T armis loaded in the insertion tube by placing the thumb on the knob and pushing the knob forwards with one hand till the arms are folded inside the inserter tube. The inserter tube length is then made as per utero cervical length measured through sound. The length of inserter is increased by pushing the knob forward. First click sound is heard when length is 4 cm. After that for every 0.5 cm there is click sound as well as measures seen on inserter tube helps provider to know the length of tube. Loaded Etherena is inserted into the cervical canal until the transparent flange comes atcervicalos level. Now the T is touching the fundus. Pull the knob back so the T is released and placed in the uterus followed by pulling the Etherena device completely out of the cervix. Now the thread is visible outside of cervix but still inside the tube. Thread is cut at 3-4 cm outside the cervix and then tube is withdrawn completely.

Etherena Loading and insertion video link (https://www.youtube.com/watch?v=wLebJ6lkDWg)

All study participants received an immediate post insertion abdominal ultrasoundperformed by the site provider. Provider measured distance from the uterine fundus to the top of IUD inmillimetres (mm).

Women were counselled and informed about procedure and risks associated. Insertions were done in outpatient department after taking verbal consent. Ethical approval was not required since it is just the client and provider's feedback gathered through this study.

Statistical analysis

All data were collected, collated and analysed using Microsoft excel tool. Data were plotted in the excel sheet and then analysed basis key characteristics and findings. Correlations and broad trends were mapped. This was done after data cleaning to ensure the consistency and correctness.

Results

Total 100 participants were enrolled (Table 1). Participants ranged from 18 to 40 years of age. Table 1 shows that the majority of the participants were aged 28-32 (49%). All women had at least 1 living child, and parity ranged from 1 to 5. Majority of the participants were literate (94%). Per the census data of 2011, 65.4 % of women in India are literate. [6] The majority of participants reported being a housewife (89%). Interval between last child birth and IUD insertion in majority of cases in between 6 weeks to 3 years. There were no statistically significant differences between groups.

Table 1: Socio demographic characteristics of the study participants

Characteristics (n= 100)	
Age	**%**
18-22	09
23-27	23
28-32	49
33-37	15
38-42	04
Total	*100*
Occupation	**%**
Housewife	89
Service	11
Total	*100*
Education	**%**
Illiterate	6
Primary education	3
Middle education	12
Secondary education	19
Senior secondary	04
Graduate	28
Post graduate	28
Total	*100*
Number of Living Children	**%**
1	32
2	36
3	20
4	09
5	03
Total	*100*
Interval between last child birth and IUD insertion	%
6 weeks- 6 months	47.96
>6 months -3 yrs.	48.98
>3 yrs.	03.06
Total	*100*

Table 2:Time taken for IUCD insertion (n=100)

Time required in seconds (Sounding, loading and insertion)	**Traditional Copper- T**	**Etherena**
60 – 100 sec	80%	100%
101 – 150 sec	20%	0

All women had successful placement of IUD. While doing the procedure provider with the help of assistant measured the time taken for sounding, loading and insertion of device by using timer.Mean time taken for the process in both groups was similar (≈90 seconds); it was more consistent in Etherena vs Copper-T.

Table 3: Post Insertion Ultrasound Results (n=100)

Distance of IUCD from the Fundus in mm	**Traditional Copper- T**	**Etherena**
1-3	44%	100%
4-5	56%	0

All cases were assessed by post-insertion ultrasonography.Table 3 describe the placement of IUD at fundus. The majority of IUDs were 3 mm or less from the fundus on immediate post-insertion ultrasound 100% and 44% respectively in Etherena v/s Copper-T group.The mean distance from the fundus was 1.82 mm and 3.7mmrespectively in Etherena v/s Copper-T group.

Provider and client Feedback

Following parameters measured using a two-point Likert scale comprising of a positive and negative response. Eg: easy/comfortable/satisfied–positive response; difficult/discomfort/not satisfied – negative response. Following are the parameters-

Table 4: Related parameters

Parameters	Traditional Copper- T	Etherena
Loading of T arms	As shown in Fig- 1bending the arms of the T arm by bringing providers thumb and index finger together, and continuing to push against the T with the insertion tube.	T arm is loaded in the insertion tube by placing the thumb on the knob and pushing the knob forwards with one hand till the arms are folded inside the inserter tube.
Setting measurement of uterine depth on inserter tube	Blue length-gauge to be set when IUD still in the partially unopened package, blue guard to be press down on the length-gauge with the thumb and index finger of one hand to keep it in place, while sliding the insertion tube with other hand until the tip of the IUCD (the top of the folded T) aligns with the tip on the measurement insert.	The length of inserter is increased by pushing the knob forward. First click sound is heard when length is 4 cm. After that for every 0.5 cm there is click sound as well as measures seen on inserter tube helps provider to know the length of tube.
Technique of placement	Withdrawal followed by second push	Simple 2 Step Operation (Push-Pull) 1.Push to load the IUD and make is ready for insertion 2. Pull to release the Copper-T 380A in the uterine cavity
Sounding	To measure uterocervical length metallic sound was used	To measure uterocervical length ESA which is a sterile disposable uterine sound was used
Overall handling of device by provider	Provider provided feedback on acceptance for use of device it includes loading of T arm, setting of uterine depth on inserter tube, and insertion technique	
	Operated by both the hands	Operated by a single hand
		Minimal Steps: The number of steps involved in loading and inserting Copper-T 380A are reduced significantly. Hence less to remember and lesser skills required
Provider Assessment /acceptability	It includes handling of device as well as client comfort or discomfort observed by provider while doing sounding and insertion	
Feedback of client immediately after Insertion	Immediately after insertion provider asked participants about whether they are satisfied with insertion procedure or not and overall satisfaction of women.	

Table 5: Feedback from study subjects (n=100)

Feedback	Traditional Copper- T	Etherena
Loading of T arms		
Easy	92%	100%
Difficult	08%	0
Setting measurement of uterine depth on inserter		
Easy	88%	98%
Difficult	12%	02%
Technique of placement		
Easy	98%	100%
Difficult	02%	0
Client comfort during sounding		
Comfortable	52%	98%
Discomfort	48%	02%
Provider Assessment /acceptability		
Easy	88%	100%
Difficult	12%	0
Overall handling of device by provider		
Satisfied	92%	100%
Not satisfied	08%	0
Feedback of client immediately after Insertion		
Satisfied	72%	98%
Not Satisfied	28%	02%

Loading of T arms were easy in all cases of Etherena and in case of traditional Copper-T 92% cases it was easy and in 8% cases loading of T arm was found difficult by provider. With a difference of using both hands for handling by traditional method compared to Etherena which was used by one hand handling which makes it more acceptable for placement by the provider. Technique of placement was difficult only in 2% of cases of traditional Copper-T insertion.

The setting of uterine depth measurement on inserter was easy in 98% vs 88% cases in Etherena v/s Copper-T. Sounding-related pain or discomfort was reported in 2% cases of Etherena group vs 48% in

Copper-T. Immediately after insertion participant's satisfaction levels reported were 98% for Etherena and 72% for Copper-T. Overall handling of device by provider were satisfactory 100% for Etherena group while in traditional Copper-T it was 92%. No case of trauma or perforation observed in either group.

Discussion

Fundal placement is an important factor for increasing IUD retention, such placement may reduce the expulsion rate and enhance overall service delivery. It is suggested in one of the study that, the distance from the top of the uterine cavity to the IUD should be 3 mm or less[7]. A distance greater than 4 mm is more often associated with symptoms such as bleeding and pain, as well as with a higher risk of expulsion or displacement[8]. In this study, the Intrauterine enabler placed the IUD at or near the fundus in all cases it is up to 3 mm. Possibly it will help in minimising side effects of IUD like bleeding and pain and possibility of expulsion. IUE is safe and easy to use with simple one hand operation.

In case of traditional Cu-T there are chances when providermay load T arm outside the package with gloved hand and in case of Etherena loading of T frame require minimal effort and always with no touch technique because of its design, hence it reduces the possibility of contamination/infection during the procedure.

Conclusion

The overall handling experience of provider was satisfactory for Etherena as it required minimal training and adequate fundal placement with quicker insertion time which aided in making the experience of women more safe with minimal handling. In conclusion, the innovative & safe insertion process using Etherena makes IUD insertions more convenient and accessible and significantly comfortable from the client perspective.

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