

Comparative study of vacuum extraction for artificial abortion by uterine cavity video monitoring and transvaginal ultrasonography guidance

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Objective: Validation of actual performance of the world's first disposable endoscopic cannula researched and developed by Chinese themselves. **Methods:** Each case is used by disposable endoscopic cannula simultaneously videotape observation and transvaginal type B ultrasonic real-time monitoring in 32 patients suction abortion surgeries. A comparison of the difference in completion of intrauterine fetal tissue clearance time and the sensitivity of judging correctly are made by two monitoring methods. **Results:** There is no significant difference in completion of intrauterine fetal tissue clearance time and the sensitivity of judging correctly by two monitoring methods. **Conclusions :** The disposable endoscopic cannula monitoring in the surgery is a more detailed and broader application.

There are approximately 150 thousands daily (or 53 millions annually) unwanted pregnancy terminated by abortion. Vacuum extraction for artificial abortion is one of the main remedies for contraceptive failure. For the past few decades, the determination for medical termination of pregnancy (MTP) procedure successfully performed is entirely depends on the experiences of the surgery performer. The indicator is that the deflation of uterine cavity, cannula tightly surrounded by uterine wall and difficult to spin. In recent year, type B ultrasonic is used in body cavity, non-invasive and real time vacuum extraction for artificial abortion. It offers MTP procedure performer real time image during procedure thus prevents possible suction leakage. However, with the significant development of Scientific and technological, an endoscope cannula which is purely invented by Chinese and has fully intellectual property right has been introduced, and clinical application has already been allowed. Such product combines a suction canal together with a high resolution camera for image transmission during the MTP procedure; actualize the real time, synchronous and full observation of MTP procedure. This study is to better understand these two innovations for MTP during clinical application for their Differences and similarities.

1. Data and Methodology

1.1 Research Objects Choosing 32 MTP patients in the hospital for the research, age between 18-37, type B ultrasonic indicated 4-8 gestational week, and without any MTP Contraindications (2 cases of 4-5 gestational week, 4 cases of 5-6 gestational week, 26 cases of 6-8 gestational week, 1 case of twin pregnancy, 1 case of intrauterine pregnancy, 1 case of mole, gravidity 1-3 times, parity 0-2 times).

Diagnose Standard: (1) The history of menopause; (2) Positive urine HCG; (3) type B ultrasonic test indicates Intrauterine pregnancy. **Eliminate Standard:** all kind of malignant period of all kind of disease or serious Systemic disease, acute inflammation of the reproductive system, vaginitis, deformity, severe hyperemesis gravidarum, body temperature $\geq 37.5^{\circ}\text{C}$, menorrhagia, History of bleeding tendency and blood disease, mental retardation, unable to pursue normal life caused by mental illness, scar uterine, abortions interval less than 6 months, participate in other clinical trials within the same month, difficulties in uterine expansion, MTP complex during uterine expansion and other MTP complex.

1.2 Research Methodology: Equipment: (1) type B ultrasonic vaginal monitor: BAISON-900A, 2.5MHz to 10MHz frequency probe. (2) Disposable Endoscopic Cannula and the endoscope video workstation produced by Dongguan Microview Medical Technology Co. Ltd. (3) All patients use Diprivan for general anesthesia.

1.3 Research programs: (1) During MTP vacuum extraction, each procedure is wholly monitor by type B ultrasonic vaginal monitor and the Endoscopic Cannula. (2) observe guideline: Use Ulead Video Studio9.0 video editor to replay the taped video by frame to compare procedures with type B ultrasonic vaginal monitor and Microview disposable endoscopic cannula on the same patient for intrauterine fetal tissue clearance time. (3) conduct β -HCG blood test 2 weeks after the MTP procedure, patient referral after the resumption of menstruation and record menstrual recovery time.

1.4 Statistical Methods: Use of SPSS17.0 software to conduct statistical analysis. Measurement data using mean \pm standard deviation, paired t test to compare the two monitoring methods (type B ultrasonic vaginal monitoring method and Microview disposable endoscope cannula) on the time difference of the removal process of intrauterine fetal tissue. The test uses of chi-square test for data frequency in order to compare the two monitoring methods on sensitivity. Due to the total number of cases <40 , category count <5 , so the Fisher exact test. Hypothesis testing using two-sided test, take $\alpha = 0.05$.

2. Conclusion: None of 32 patient cases indicated suction leakage, all cases recovered to non-pregnant state based on β -HCG blood test result and menstrual recovery time shown to be 30.75 ± 2.51 days.

Table 1 Compare the two methods in monitoring intrauterine fetal tissue clearance time of completion

	MTP procedure time (minute)	Standard deviation	Standard error of the mean	t	P
Microview disposable endoscopic cannula	4.27	0.45	0.08	0.139	0.890
type B ultrasonic vaginal monitoring method	4.24	1.15	0.20		

As shown on table 1, Video shows that there is no significant difference on the MTP procedure between the two methods. The standard deviation is larger on the type B ultrasonic vaginal monitoring method is due to there was echo image happened during MTP procedure on one of the study cases, the whole procedure process last for 10.2 minutes.

Table 2 Comparison of the sensitivity of embryonic tissue removal in two real-time monitoring during surgery

	Able to determined	Unable to determined
Microview disposable endoscopic cannula	33	0
Type B ultrasonic vaginal monitoring method	32	1

Fisher's exact test: $P = 0.5$, it indicates that the sensitivity of the removal process of intrauterine fetal tissue using the two monitoring methods is not significant.

3. Discussion:

Microview disposable endoscopic cannula is a latest high-tech product invented by Chinese independently ; It equipped with a disposable high resolution video endoscope, the Endoscopic cannula offers a combination of convenience and precision to realize the real time monitoring of the whole MTP procedure. The Endoscopic cannula was

designed to be covered by a water-resistant surface, this design assures the image definition of Embryonic tissues (Figure 1) and intrauterine birth control ring (Figure 2) during procedure without the uterine distention process. Therefore, Microview disposable endoscopic cannula can also be used in IUD removal procedure including the removal of the remaining fragment, metal and other leftover of the IUD in addition to the MTP vacuum extraction.

Microview disposable endoscopic cannula shows a high definition image of sac-like structure (Figure 3) and villous vascular blood flow. The translucent membranous Embryo sac indicates approximately 8 weeks of pregnancy; the Microview disposable endoscopic cannula was able to show the rotation of the embryo vaguely. In the mole extraction case study, use Microview disposable endoscopic cannula can clearly see the white rounded shape mole tissue (Figure 4) and the adhesion between mole tissue and the uterine wall. Due to the softness of patient's uterine, the stylet enters deeper than the depth of the uterus, in consideration of uterine perforation, before the extraction starts and Patients with stable vital signs, the procedure uses Microview disposable endoscopic cannula, under the circumstance of clearly viewing cervical mucosa and endometrium structure and ensure the cannula was inside the uterus, we complete the mole extraction process.

As a result of without uterine distension, Microview disposable endoscopic cannula makes contact and closely monitors uterine cavity, i.e. when cannula enters uterus it is surrounded by the uterine wall when observing the uterine wall. While using Hysteroscopy after fluid uterine distention, there is distance between camera and the observing object, thus the image is three-dimensional. Therefore, the image captured by Microview disposable endoscopic cannula and Hysteroscopy is different.

Type B ultrasonic monitoring method is used in MTP procedure prevalently in recent years. Type B ultrasonic monitoring method visualizes the uterus size, location, degree of flexion and the gestational sac implantation site (Figure 5, Figure 6), guides the surgery performer the correct intrauterine operation direction and depth, dynamic observation of the MTP procedure, observe whether the gestational sac is removed completely. Type B ultrasonic monitoring method is a useful MTP monitoring method for preventing intrauterine tissue removal leakage and uterine perforation [2-5].

However, in clinical practice, we found that the Type B Ultrasonic monitoring method can not prevent intrauterine tissue removal leakage in MTP procedure completely, the reason of that except the operator's own technical factors, the type B ultrasonic has its own limitation: (1) Type B Ultrasonic monitoring method shows Surface of the uterus while it is three-dimensional, under the circumstance of MTP procedure process, the uterus is not still thus the performers need to stop the process and position target tissue before they can start the process again; (2) the image resolution limitation of Type B

Ultrasonic monitoring method; (3) when intrauterine fetal tissue is tightly close to uterine wall, the determination of target tissue using Type B Ultrasonic monitoring method can be very difficult. In this study, there was a patient Menopause for 7 weeks and 3 days, Microview disposable endoscopic cannula could not found any intrauterine fetal tissue during MTP procedure while the Type B Ultrasonic monitoring method showed abnormal echo, the echo remained even after repeat vacuum extraction, the procedure process last for 10.2 minutes. The further follow record shows patients stop vaginal bleeding 5 days after the MTP procedure, β -HCG blood test indicated Non-pregnant state 14 days after the procedure, menstrual recovery happened 32 days after the procedure. The case study shows that Type B Ultrasonic monitoring method used in MTP procedure can be difficult to determine if intrauterine fetal tissue is removed completely, after all, outer body cavity monitoring is more susceptible as it can be interfered by various factors.

Hysteroscopy technique can also be used for direct vision MTP vacuum extraction, at the moment, it mostly used in: metrectopia, uterine malformation, history of caesarean section, abnormal position of implantation (uterine horn, uterine wall, and caesarean section scar), postpartum hemorrhage, placenta accrete, lactation, patients with history of incomplete abortion, etc^[6,7]. There is some online promotion of “hysteroscopic fetal tissue removal surgery” introduced by some hospitals, however, there is no study on hysteroscopy used in normal MTP vacuum extraction, this is not only due to the high cost, but more importantly the unstable fluid pressure during uterine distension may increase the chance of complications of using uterine distension fluid such as water poisoning and disseminated intravascular coagulation (DIC) caused by embryonic tissue into the maternal blood circulation.

Both type B ultrasonic monitoring method and Microview disposable endoscopic cannula can achieve the clinical objective of removing intrauterine fetal tissue completely. Microview disposable endoscopic cannula shows the intrauterine fetal tissue and its position clearly inside the uterus; guide the procedure performer to induct the procedure in a direct image. Microview disposable endoscopic cannula ensures the procedure performer sees the shape, size and position of the intrauterine fetal tissue during MTP procedure. There, in compare with the type B ultrasonic monitoring method, Microview disposable endoscopic cannula has more advantages as it is a more detailed, more promising and can be used in a broader range.

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Appendix (Figure):

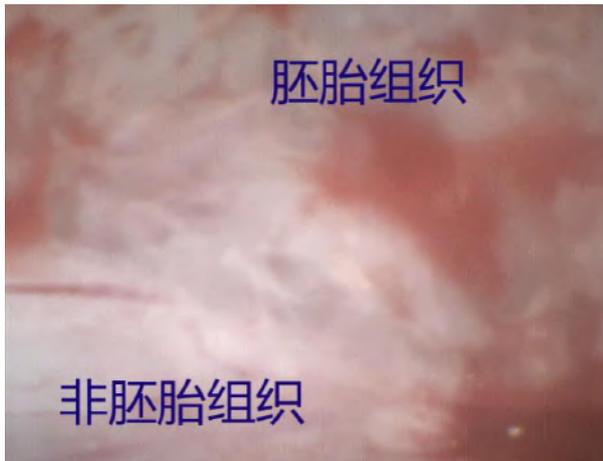


Figure 1 : Intrauterine fetal tissue

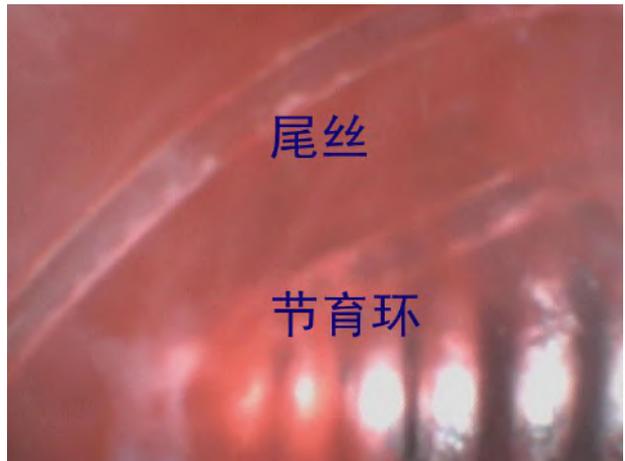


Figure 2 : Intrauterine contraceptive ring (IUD)



Figure 3 : Branch of sac-like structure



Figure 4: mole tissue



图 5 : Microview disposable endoscopic Cannula

flattened embryo sacs, and is not broken



图 6 : Microview disposable endoscopic Cannula

in-between of two sacs