



USE OF MISOPROSTOL IN ABORTION ON MEDICAL GROUNDS – OUR CLINICAL EXPERIENCE

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ABSTRACT

Purpose. In clinical practice in hospital conditions, the preferred choice of behavior regarding fetal anomalies is to perform a medical abortion after the opinion of a specialized committee in the hospital. There are no observations conducted by other authors on abortions related to termination of pregnancy for medical reasons at a different time. The team conducts its observation in hospital conditions.

Material/Methods: Conducted own retrospective study for the period January 2021 – February 2024 with the participation of 45 patients who went through a pregnancy termination committee on medical grounds. All women who passed through the committee for medically indicated abortion, in which fetal anomalies incompatible with life or severely debilitating were found, were examined. Women are at different stages of pregnancy, age, education, number of pregnancies and births, concomitant diseases, a type of test to diagnose abnormalities in the fetus (invasive and non-invasive). The type of abnormality that is the cause of an abortion on medical grounds has also been investigated. The dosage applied is- 1st tablet of 400 mg Misoprostol per vagine, second and third tablets in 3 hours sub buccal, the maximum dose is 5 tablets in 24 hours or 2000 microgram Misoprostol.

Results. For 88,9% of the cases, they have a positive opinion of the commission in the hospital structure, and 11,1% have a refusal. Group matching of patients was performed by education and whether they had good outpatient follow-up, regardless of the duration of pregnancy. Patients with higher education had better outpatient follow-up ($\chi^2=15.497$, $p=0.000$) than those with secondary and primary education. There was a significant association between the dosing regimen and pregnancy severity; the relationship between the two-dose regimen was significant ($\chi^2=53.862$, $p=0.000$), and the three-dose regimen was highly successful in 73.3% of cases.

Conclusion. The correct choice of method of application of the therapeutic regimen requires preliminary and detailed medical preparation of the patient and good clinical experience of the treating doctor. The applied therapeutic approach reduces the risk to the patient and has a rapid recovery period. Early and timely diagnosis has an important informative value.

Keywords: malformations, prenatal diagnosis, Commission medical abortion, Misoprostol, therapeutic scheme,

INTRODUCTION

Medical abortion is the preferred method with proven high safety for patients, confirmed by a number of studies in which more than 89% of women have successfully terminated their pregnancy. For 11% of those who passed, there is a categorical refusal of the commission to perform a medical abortion due to a lack of compliance with the necessary documents and studies - fetal morphology, non-invasive prenatal test, or other genetic tests. Refused pregnant women were not followed up as they did not contact the commission again. Most women were either satisfied (64.8%) or very satisfied (28.6%) with their stay in the ward and the therapeutic abortion. Ninety-four percent of women reported that they would recommend the procedure to a friend because it is less painful and does not require a bulge stay. [1, 2]

A number of hospital structures have introduced medicated abortion as a safe method at 9-12 weeks of gestation, and 92.1% offer home administration of Misoprostol. For home administration of Misoprostol, most studies have focused on the safe use of Misoprostol when a woman wants to have an abortion but cannot devote her time to a hospital stay. They give instructions on how to take the drug and what to monitor. Compared to women who have a surgical abortion, women who have a medical abortion had a higher chance of miscarriage at 4-6 weeks (adjusted OR 2.33; 95% confidence interval 2.28-2.38). The waiting time between registering and obtaining an abortion request to termination was reduced from 11.3 days in 1998 to 7.3 days in 2013. [3, 4]

The use of Misoprostol is based on a protocol to prevent pregnancy and reduce the risk of complications and infections. When taking Misoprostol, side effects may occur - hypersensitivity to the drug, pregnancy and amenorrhoea for more than 49 days (there is a teratogenic effect in failure and subsequent refusal to complete the abortion), diarrhoea, pain, bleeding. The protocol follows the first 24 hours, after which further treatment is at the discretion of the attending physician [5]. The protocol is successfully applied in several obstetric practices (Table 1.). The International Federation of Gynecology and

Obstetrics (FIGO) and WHO produce these dosage guidelines. They are based on those originally produced by

the Bellagio group in 2007 but have been updated regularly since [6].

Table. 1. Misoprostol Only Recommended Regime / Updated 2018 [6]

<13 weeks' gestation	13–26 weeks' gestation (An additional dose can be offered if the placenta has not been expelled 30 minutes after fetal expulsion)	>26 weeks' gestation	Postpartum use
Pregnancy termination 800 µg sl every 3 hours or pv / bucc every 3–12 hours (2–3 doses)	Pregnancy termination 13–24 weeks: 400 µg pv /sl /bucc every 3 hours 25–26 weeks: 200 µg pv /sl/bucc every 4 hours	Pregnancy termination 27–28 weeks: 200 µg pv/sl/bucc every 4 hours >28 weeks: 100 µg pv/sl/bucc every 6 hours (An additional dose can be offered if the placenta has not been expelled 30 minutes after fetal expulsion)	Postpartum hemorrhage (PPH) prophylaxis 600 µg po (x1) or PPH secondary prevention (approx. ≥350ml blood loss) 800µg sl (x1) (For community based use)
Missed abortion / miscarriage 800 µg pv every 3 hours (x2) or 600 µg sl every 3 hours (x2)	Fetal death 200 µg pv/sl/bucc every 4–6 hours	Fetal death 27–28 weeks: 100µg pv/sl/bucc every 4 hours >28 weeks: 25µg pv every 6 hours or 25µg po every 2 hours (Reduce the dose for woman with previous caesarean section)	PPH treatment 800 µg sl (x1)
Incomplete abortion/ miscarriage 600 µg po (x1) or 400 µg sl (x1) or 400–800 µg pv (x1)	Inevitable abortion / Miscarriage 200 µg pv/sl /bucc every 6 hours (Including ruptured membranes where delivery indicated)	Induction of labor 25µg pv every 6 hours or 25µg po every 2 hours (*Previous cesarean delivery or transmural uterine incision is a contraindication * Use in grandmultiparous with caution * Induction of labour should be carried out in facilities where cesarean section can be performed * Close maternal & fetal monitoring are needed)	
Cervical preparation for surgical abortion/ miscarriage 400 µg sl 1 hour before procedure or pv 3 hours before procedure	Cervical preparation for surgical abortion/ miscarriage 13–19 weeks: 400 µg pv 3–4 hours before procedure >19 weeks: needs to be combined with other modalities		

Various pilot schemes have been implemented, which, after the second intake of Misoprostol, reduce the time to complete an abortion by about 77 minutes [7], no later than the 6th hour. This method is usually effective up to 10 weeks after the last menstruation, but the exact effectiveness can vary.

All abortion procedures, including medical abortion, must be carried out under the supervision of qualified medical personnel providing all necessary information and support [8, 9]. This study established the successful use of Misoprostol in performing an abortion on medical grounds, in a hospital environment, in the presence of serious diseases of the fetus. A means of choice is the possibility to administer the therapeutic dose as early as possible to the patient without any conditions and requiring special preparation. The study has informative and clinical value on the effect of misoprostol administration in the Department of Gynecology on women at different periods of pregnancy.

The objective of the study is to determine the scheme of administration of Misoprostol at hospital in women with abnormalities in fetal development, targeted for abortion on medical indications and to establish studies for optimizing the diagnostic management of the commission.

MATERIAL AND METHODS

In Bulgaria there is a marked resistance to innovative methods and technologies and to changing attitudes

of behavior. However, it is a means of the choice of the doctor performing the medical abortion to choose not only the cost-effectiveness but also to minimize the hospital stay and complications for the benefit of the patient and his safety. The study conducted among patients who went through a medical abortion committee is the first in the country and confirms the safety and efficiency of misoprostol administration under medical supervision, women recover faster, and their stay in the medical institution is less. The observation carried out in women with therapeutic abortion established the effectiveness of the regimen of Misoprostol under medical supervision, in the following scheme - 1st tablet through per vagine, second and third tablet sub buccal, every 3 hours; next tablets every 6 hours. The maximum dose for 24 hours is 2000 mg misoprostol (5 tablets). Applying the worldwide experience model, a number of hospital structures minimize the hospital costs associated with performing the abortion procedure on medical grounds.

The inclusion criteria were as follows: all women who have applied to the commission for abortion on medical indications in the Gynecology Department of the Obstetrician-Gynecological Hospital; confirmed abnormality of the fetus with the presence of two or three diagnostic invasive and non-invasive methods; women with a positive opinion received from the commission for abortion on medical indications; application of a therapeutic regimen with Misoprostol.

The exclusion criteria were as follows: women with requesting abortion at will under 12 weeks of gesta-

tion; conduct only one diagnostic method of examination confirming the presence of an abnormality of the fetus; no medical reason on the part of the fetus for termination of pregnancy; withdrawn application by the commission; application of other methods of termination of pregnancy; patients with other diagnoses.

Methodology. A retrospective study of the activity of the commission for termination of pregnancy on medical indications of the Specialized Obstetric and Gynecological Hospital in Varna, Bulgaria, with the third level of competence of the Department of Gynecology for the period January 2021 – February 2024. There were 45 cases of pregnant women between 8 and 28 gestation weeks who were diagnosed during routine tests with fetal abnormalities that are incompatible with life or lead to a high disability after birth.

The survey data and the results are processed and

presented graphically through Microsoft Word (2016) è Microsoft Excel (2016). Data processing was carried out with the statistical product IBM SPSS 19.0. For statistical data processing, the following methods are used: descriptive analysis; graphical analysis; correlation analysis (Pearson correlation) to search for statistical significance of the signs in the studied groups. Test χ^2 - to check hypotheses for the presence of a link between category variables. Cases where $p < 0.05$ are considered statistically significant.

RESULTS

Demographic characteristics. The distribution of the sample by age and term of pregnancy is presented in Fig. 1 and 2, the figure graphically represents the distribution of pregnant women by age and term during pregnancy.

Fig. 1. Distribution of patients by age in the study group of 45 women (*x-axis*: age group; *y-axis*: number of patients)

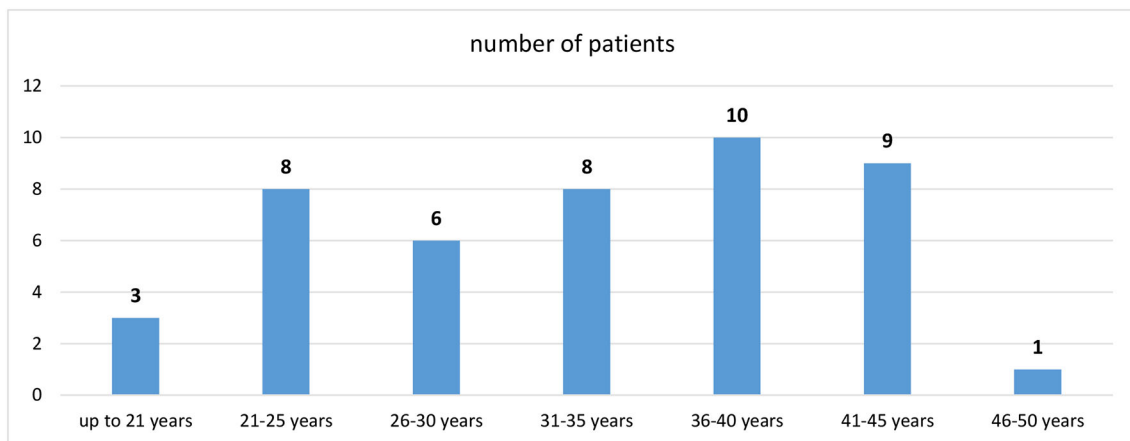
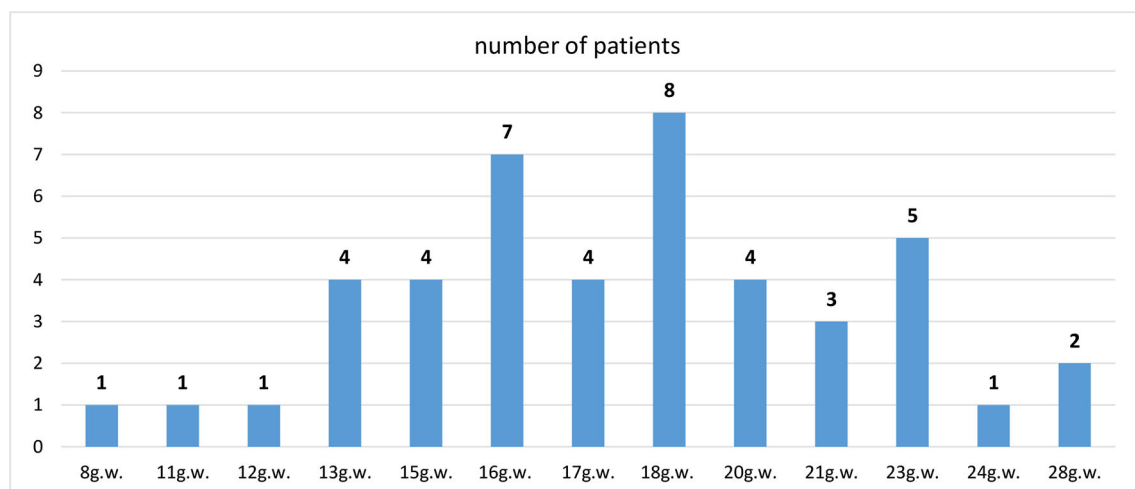


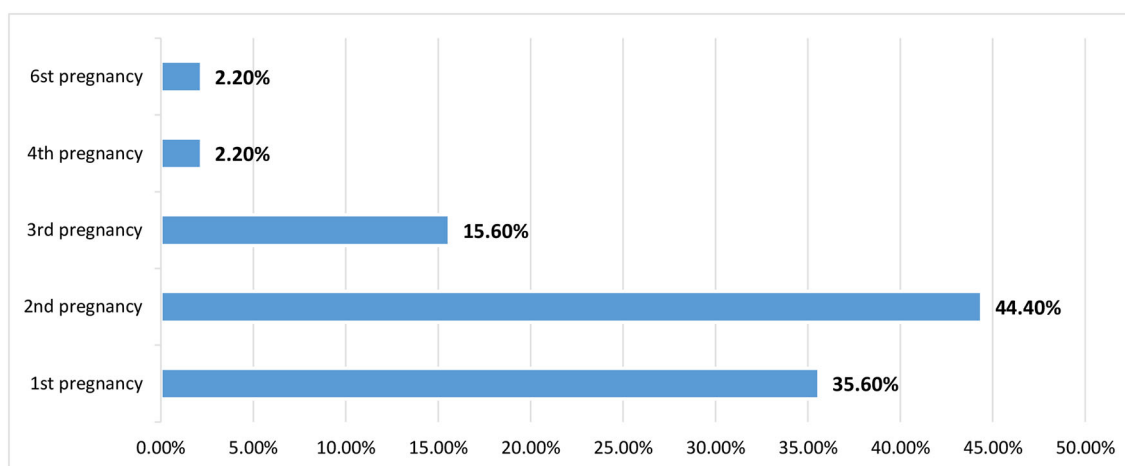
Fig. 2. Distribution of patients in the study group of 45 women according to the term of pregnancy (*x-axis*: term of pregnancy (g.w.); *y-axis*: number of patients)



In terms of pregnancy sequence, 44.4% (20) had a second pregnancy (Fig.3), first pregnancy was 35.4% (16), third pregnancy was 15.6% (7) and 4th and 6th pregnancy was for 2,2% (1) of cases reviewed. Women were grouped by education - 46.7% (21) had higher education, and 17.8% (8) had primary education. Secondary education had 35,6% (16) of cases reviewed. Women were grouped by education - 46.7% (21) are with higher education and 17.8% (8) with primary. Secondary education had 35,6% (16) of cases reviewed.

With age, pregnancies also increase (from 20 years to 50 years of age), which is a natural dependence and desire for the performance of reproductive functions. A close correlation has been found between the number of births of pregnancy and age (in groups 36-40 and 41-45 years) of the patients ($\chi^2=37.135$, $p=0.042$) (in these two age groups, the number of consecutive pregnancies is higher). The more highly educated patients performed detailed prenatal diagnostics in their outpatient follow-up ($\chi^2=15.497$, $p=0.000$).

Fig. 3. Grouping of patients by order of pregnancy in the observed group of 45 respondents



As we age, pregnant women report more comorbidities - extragenital (genetic, endocrine, neurological) and genital (gynecological diseases, sterility) ($\chi^2=84.351$, $p=0.005$). Of the 45 patients who passed, 88,9% received a positive opinion from the commission towards the medical institution. Of the cases examined 8,9% (4 of

the cases) have been refused by the commission and 2,2% (1 case) have withdrawn the application for examination before it went through the commission.

The established prenatal pathology of the fetus varies depending on the genetic exposure and modification of the syndrome-symptomatic complex (Table 2).

Table. 2. Types of congenital malformations which caused abortion in the 45 pregnant women studied

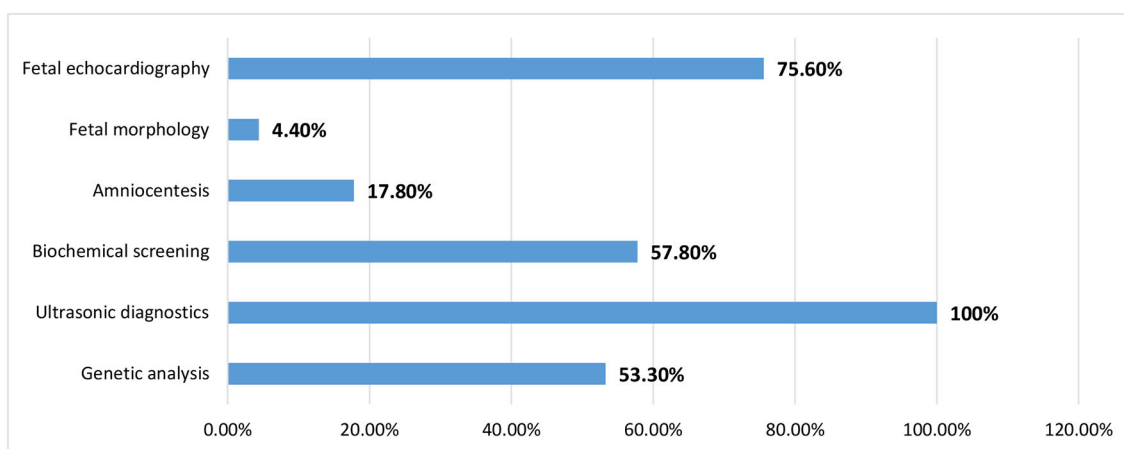
Valid	Frequency	Percent	Cumulative Percent
Folo's tetralogy	1	2.2	2.2
Omphalocele / gastroschisis	1	4.4	8.8
abnormality of the excretory system – Megacist	4	8.9	13.3
Polymalformative syndrome	7	15.6	28.9
Congenital heart disease malformation	3	6.7	35.6
Edwards syndrome	6	13.3	48.9
Klinefelter syndrome	1	2.2	51.1
Down syndrome (trisomy 21)	10	22.2	73.3
Defect in placental attachment	1	2.2	75.6
Hydrocephalus	1	2.2	77.8
Microcephaly	1	2.2	80
Niemann-Pick disease (heterozygous change in gene SMPD1)	1	2.2	84.4
Not established	3	6.7	91.1
Lemon sign syndrome	1	2.2	93.3
Skeletal dysplasia	2	4.4	97.8
Active Syphilis of the mother	1	2.2	100
Total	45	100	100

Diagnostic methods for registering deviations in fetal development refer to ultrasonic diagnostics, carrying out fetal morphology at 2 stages (early -between 11-14 gestational week for measurement of nuchal translucence and late fetal morphology between 20 and 22 weeks of pregnancy), carrying out fetal echocardiography, non-invasive prenatal test, in case of suspected deviations and after explanation of the risks of carrying out the test, carrying out amniocentesis in specialized prenatal centers. Conducting biochemical screening - a non-invasive test to detect the most common genetic abnormalities only from the mother's blood sample, without any risk to the fetus. If a high-risk test is detected, confirmation by amniocentesis or additional genetic testing is required.

Early diagnosis is leading in terms of medical behavior, according to the wishes of the pregnant woman

and the serious economic and social consequences of the possible birth of a damaged child (These are methods applied in Bulgaria for the diagnosis of fetal abnormalities. 2 or 3 diagnostic methods proving the pathology in the fetus are required for the decision of the commission, Fig. 4). Nearly 80% of the patients performed more than three diagnostic methods to determine the abnormality in fetal development ($\chi^2=21.339$, $p=0.002$). The remaining patients did not carry out the necessary tests, therefore, did not receive an opinion from the commission and were instructed to carry out further tests on the foetus. As women age, they prefer genetic testing ($\chi^2=27.154$, $p=0.000$). All patients were given ultrasound diagnostics according to the Medical guidelines of Obstetrics and gynecology. There is a significant association between age and the presence of malformation in the fetus ($\chi^2=131.517$, $p=0.009$).

Fig. 4. Diagnostic methods 45 women who had a medical abortion



* % is greater than 100% due to more than two diagnostic methods to establish/prove an abnormality in fetal development.

Own Results

For all patients applying for termination of a pregnancy, the specialized committee - Commission for Interruption of Pregnancy, on medical indications to the Department of Gynecology of Specialized Obstetrics and Gynecology Hospital, issues an opinion according to the instructions of the requirements of the medical normative in Obstetrics and gynecology from 2021. All patients hospitalized after a positive opinion of the commission for termination of pregnancy carried out a full volume of diagnostic and therapeutic procedures, according to the instructions of the regulations (National Health Insurance Fund and Medical Standard for Obstetrics and Gynecology). The hospital stay is carried out by clinical Route 4-4.1 (up to 13 g.w.) and 4.2 (over 13 g.w.).

The prescribed schedule of Misoprostol in the gynecology department of pregnant women with a positive opinion of the commission is: 1st tablet of 400 mg Misoprostol per vagine, second and third tablets in 3 hours sub bucal, the maximum dose is 5 tablets in 24 hours or 2000microgram Misoprostol. At 73.3% of cases, a three-fold scheme was applied with Misoprostol. In

11.1% of cases, no therapeutic regimen was administered due to refusal to perform medical abortion. As the term of pregnancy progresses, a higher therapeutic regimen is applied - application of uterotonics to stimulate childbirth ($\chi^2=53.862$, $p=0.000$). The type of malformation not detected affects the choice of the regimen of administration by the specialist physician, which affects the assessment of the patient's needs ($\chi^2 = 55.838$, $p=0.006$). They are present at birth (continued risk of pregnancy) and are often symptomatic, causing morbidity and pain. An accurate clinical history and cross-sectional imaging are critical for diagnosis and for devising management. Early diagnosis is very important for determining the subsequent behavior because multiple malformations are associated with various pathological conditions, not only in the fetus but in terms of attachment of the placenta, changes in hemodynamics or affecting other systems of the maternal organism.

A one-time application of Misoprostol has the best effect in the early term of pregnancy between 8-13 g.w. ($\chi^2 = 30.537$, $p=0.006$) when using Misoprostol in an early period, -1 tablet per vagine and one tablet sub bucal, the

effectiveness of the applied scheme is reported, therapeutic abortion is performed, and effect up to the 6th hour ($\chi^2=8.133$, $p=0.004$). The three-time administration of the drug regimen showed an effect between 6 and 12 hours. ($\chi^2=74.000$, $p=0.000$) and a gestation period of 12-20 g.w. ($\chi^2 = 38.858$, $p=0.025$). In case of early detection of anomalies and ultrasound confirmation of intrauterine pregnancy, one-stage termination of pregnancy is preferred (1 tablet through per vagine and 1 tablet sub buccal), in the case of a longer period of pregnancy, it is necessary to apply the whole scheme of 5 tablets.

A statistical association was observed between the pregnancy sequence and the effect of the administered drug regimen ($\chi^2=15.591$, $p=0.049$). The test of the Kolmogorov-Smirnov confirms the importance of the relationship between the term of pregnancy and the time effect of the administered drug regimen ($p=0.000$). The Kolmogorov-Smirnov Goodness of Fit Test (K-S test) compares data to see if they have the same distribution. It is also used to test the assumption of normality in the dispersion analysis for a sample of less than 50 respondents. Test Kolmogorov-Smirnov [10] indicates whether a sample comes from a population with a specific distribution and is based on the empirical distribution function itself (CDF). There is no correlation between the diagnosed pathology of the fetus and its sex ($\chi^2=33.569$, $p=0.391$).

The main limitation of the study: The study has several limitations. The sample size is small (less than 50), so representativeness was checked with the Kolmogorov-Smirnov independence test. The study was conducted in one medical facility, and no comparison was made with other structures in the same territory. The commission has the highest level of competence and covers high-risk cases among those indicated for medical abortion.

DISCUSSION

In recent years, the World Health Organization has worked hard to improve the safety and quality of abortion as a procedure. Good prenatal diagnosis is an important condition for early implementation of the necessary therapeutic procedures, which reduces the psychological effect on the family unit and allows genetic and family consultation at reproductive age. In the case of diagnosed fetal abnormalities, a personal and medical decision is made to terminate the pregnancy. There are very few reports about this matter. The World Health Organization recommends two regimens for safe and effective medication abortion care throughout pregnancy: Misoprostol on its own or mifepristone in combination with Misoprostol. The various authors present the results of their studies in early pregnancy and the correlations they have found in the use of drugs for the termination of unwanted pregnancies. According to Briozzo L, et al. these medications, when used correctly, successfully terminate 80-95% of pregnancies without the need for surgical intervention, depending on regimen and pregnancy duration [11]. In their research from 2016 (Int J Gynaecol Obstet.- “Over-

all and abortion-related maternal mortality rates in Uruguay over the past 25 years and their association with policies and actions aimed at protecting women’s rights.), the authors present the observations carried out. Misoprostol alone is likely the most common method of medication abortion used worldwide—largely because, unlike mifepristone, Misoprostol is widely available in many places over the counter without a prescription and at a low cost. The recurrence of pregnancy without clinical observation has grown globally and is widely credited with reducing maternal morbidity and mortality. Various studies have established the self-managed use of Misoprostol-alone regimens of medication abortion without a prescription, to which choices are directed to carry out the rapid and safe evacuation of the fetus. [12, 13]. A small proportion of women who bought this medication have visited a doctor because of complications or infection. A large study by Akinyemi A, et al. in Nigeria tracked the independent and successful use of Misoprostol, with 94% of those who used the drugs on the instructions of pharmacists reporting a complete abortion without surgery within 1 month of taking the drug [14]. Currently, Misoprostol is used around the world in gynecology and obstetrics, however, none of these indications are Food and Drug Administration in the US (FDA) approved [15].

The reason for this is the indisputable fact that almost all complications of abortion can be prevented through family planning, contraception and high-quality service termination of pregnancy. Misoprostol alone is a safe, effective, and acceptable regimen for abortion care that, with increased accessibility, has the potential to greatly expand access to medication abortion in a variety of contexts. The author came to this conclusion in his clinical work when he introduced medical abortion as a means of choice in a gynecology department for patients indicated for abortion. The normative provision of the country allows an abortion over 12 weeks of gestation to be performed only for medical reasons and in a hospital. Women with identified problems with the fetus go through a commission, which comes out with a decision on whether it is legal to perform an abortion for medical reasons. The author examines all received applications in detail. Women who meet the conditions (thorough tests, examinations and fetal observations performed) are given a medical abortion with Misoprostol. The scientific value of observation is reduced to establishing a regimen of administration in a hospital environment for therapeutic abortion, monitoring and control of administration, monitoring the effect of misoprostol administration for conducting therapeutic abortion. The women were followed up during the hospital stay, no complications or discomfort were found, no side effects have been identified or reported.

In this regard, the WHO has issued a specialized guide on “safe abortion”, in which good practices are well visualized.

CONCLUSION

Medical abortion has both advantages and inconveniences (risk of lack of effect). It is a treatment plan of choice because it avoids surgical intervention, provides high security, and is less invasive, given the nature of the application. Medical abortion should become

part of routine practice in pre-hospital and inpatient medical care because it has proven to be an effective and safe method of termination of pregnancy. Its advantages are undeniable against the background of low risk and lack of invasiveness.

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