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FIGO INITIATIVE

Introduction of misoprostol for the treatment of incomplete abortion beyond 12 weeks of pregnancy in Benin

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ABSTRACT

Improving the care of women who have undergone a spontaneous or induced abortion is an important step in reducing abortion-related morbidity and mortality. Both the International Federation of Gynecology and Obstetrics (FIGO) and the World Health Organization recommend the use of manual vacuum aspiration (MVA) and misoprostol rather than sharp curettage to treat incomplete abortion. MVA was introduced into the public healthcare service in Benin in 2006 and since 2008 misoprostol has been available in 3 large maternity hospitals. The present study opted to use an oral dose of 800 μg and not to limit to pregnancies of up to 12 weeks, but to include women with second trimester abortions. After 5 years, results show that around three-quarters of the women treated with misoprostol at 13–18 weeks of pregnancy required MVA to complete uterine evacuation and approximately one-quarter had severe bleeding, confirming that the indication of misoprostol for incomplete abortion should be limited to pregnancies of up to 12 weeks.

1. Introduction

Maternal mortality has been an issue of great concern in Benin for decades. The high maternal mortality ratio has remained virtually unchanged, from 474 maternal deaths per 100 000 live births in 2001 to 397 in 2006. Accordingly, approximately 1500 women die each year in the process of giving birth. It is estimated that 15% of those deaths are related to induced, mostly unsafe, abortions [1].

In an effort to achieve the fifth Millennium Development Goal, in 2006 Benin implemented a policy for preventing unsafe abortion and improving postabortion care. Initially, manual vacuum aspiration (MVA) was introduced to replace sharp curettage, followed by the adoption of misoprostol for the treatment of incomplete abortion.

There is already ample experience on the use of misoprostol for the treatment of incomplete abortion, as reflected in publications in scientific journals and in the recommendations of the World Health Organization (WHO) and the International Federation of Gynecology and Obstetrics (FIGO) [2,3]. Most of the literature, however, refers to clinical trials in which the recommendations are strictly followed. Few publications deal with experiences in which those recommendations are applied in low-resource countries such as Benin and in hospitals in which the demand of women requesting postabortion care is heavy. In addition, to the best of our knowledge there have been no publications on the success rate of misoprostol when larger doses are used to treat an incomplete abortion beyond 12 weeks of pregnancy.

For that reason, 5 years after the introduction of misoprostol for the treatment of incomplete abortion in 3 maternity teaching hospitals in Benin using a protocol that differs from the one usually recommended, it is time to review this experience and evaluate its results, particularly in cases in which the drug was used after 12 weeks of pregnancy. The present article presents an analysis of the data collected throughout the entire period in which this pioneering experience was applied in this region.

2. Materials and methods

A descriptive, prospective study was conducted over a 5-year period in 3 maternity hospitals in Cotonou, Benin: the Obstetrics and Gynecology Clinic (CUGO) at the Hubert Koutoukou Maga National Teaching Hospital; the Lagoon Mother and Child Hospital (HOMEL); and the Ménontin Maternity Hospital.

The study population consisted of all women admitted to the 3 aforementioned hospitals between January 1, 2008, and December 31, 2012, with a diagnosis of incomplete abortion. Women were not included in the study if they had had a complete abortion that did not require active treatment or if they had severe complications requiring immediate action—a situation in which there would be no time or opportunity to collect data. They were also not included if gestational age was more than 18 complete weeks or if the woman was unable to provide information on gestational age and physical examination showed a uterine size compatible with the late second trimester.

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A team of midwives and physicians, who were either specialists in obstetrics and gynecology or residents in training, received the women consulting for incomplete abortion. The diagnosis of incomplete abortion was based on a clinical examination and on an ultrasonography scan carried out in the emergency department. Women were candidates for misoprostol treatment if they were hemodynamically stable and uterine contents at ultrasonography were less than 20 mm. They were counseled on the option of medical treatment, and informed about the other alternatives available, thus the women were given the right to choose the method they preferred. Counseling also emphasized the need to return for a follow-up visit at which they would be offered an effective contraceptive method. Together with the advantages, the women were also informed of the possible adverse effects of medical treatment, principally pain and bleeding but occasionally diarrhea, hyperthermia, and chills.

Patients who opted for medical treatment received 800 μg of misoprostol (Cytotec R; Pfizer, NY, USA) in the form of four 200-μg tablets placed under the tongue in the presence of the provider and kept in place for a period of 30 minutes.

Follow-up appointments were made for 3 days later to verify progress and for 15 days later when ultrasonography was performed to monitor uterine contents. If the uterus was empty or ultrasonography showed minimal uterine contents, but the woman was asymptomatic, the procedure was considered successful and no further treatment was given. If the uterus was not empty and the woman was bleeding or still cramping, the procedure was considered to have failed and the woman underwent MVA unless she was stable and wanted to try a second 800-μg dose of misoprostol. In the latter case she received a second dose of misoprostol and an appointment was set for 10–15 days later. If the uterus was still not empty after this second follow-up, the patient underwent MVA.

Once it was confirmed that the uterus was empty, the women were offered a contraceptive method of their choice; however, particular emphasis was placed on the advantages of long-acting reversible contraceptives (LARCs) such as the copper T 380 intrauterine device (IUD) and the Jadelle (Bayer Healthcare, Berlin, Germany) contraceptive implant.

The present paper describes the proportion of women with an incomplete abortion who were treated with misoprostol in the 3 study hospitals, and how this proportion changed over time. It also shows the distribution of these women according to gestational age at the time of the abortion, the adverse effects recorded, the results of the ultrasonography scans at the follow-up control visit, and the success rate defined by the proportion of women who did not require MVA to complete uterine evacuation. The associations between gestational age and adverse effects and between gestational age and the success rate were also analyzed, as well as which contraceptive methods were adopted by the women during the follow-up period. Evaluation of the adverse effects was based on the patient's report and on the clinical examination and ultrasound scan. The amount of bleeding was evaluated according to the number of completely saturated tampons used by each woman over a 24-hour period. Bleeding was classified as heavy if the number of tampons used over 24 hours was more than 4.

Data on the variables studied were collected prospectively using specially designed clinical forms on which the data listed above had to be recorded. The same forms were used in all 3 hospitals. The data were checked manually to reduce possible data collection errors. Excel 2007 (Microsoft, Redmond, USA) was used for data entry and cleaning. The associations between gestational age and success rate and between gestational age and the incidence of adverse effects were evaluated using Epi Info (Centers for Disease Control and Prevention, Atlanta, USA).

Every woman who elected to use misoprostol for the treatment of an incomplete abortion signed an informed consent form. The study was evaluated and approved by the Internal Review Board of the School of Health Sciences, University of Benin.

3. Results

A total of 3139 women were admitted with an incomplete abortion at the 3 participating hospitals over the 5-year period between January 2008 and December 2012. The number of patients seen at the CUGO and Homel hospitals during the 5-year period was similar (n = 1150, 36.6% vs n = 1190, 35.3%, respectively), while only 880 cases (23.1%) were attended at the Ménontin Maternity Hospital.

After examination, 630 of the 3139 women were diagnosed as having had a complete abortion requiring no treatment. Of the remaining 2509 women, 48.1% (n = 1277) were treated with MVA and 21.4% (n = 537) with misoprostol. The number of women treated with misoprostol comprised less than 10% of all the women during the first year; however, this proportion increased to 10%–20% in the different hospitals in the second year, stabilizing at around 25% in the fourth year and decreasing slightly to just over 20% in the fifth year of observation (Table 1).

The gestational age of the 537 women treated with misoprostol was: 10 weeks or less (64.1%; n = 344), 11–12 weeks (14.9%; n = 80), 13–14 weeks (13%; n = 70), and 15–18 weeks (8.0%; n = 43).

Misoprostol was administered either in a single 800-μg dose or in two 800-μg doses for a total of 1600 μg. In 55.9% of the cases (n = 300) only one 800-μg dose of misoprostol was required, whereas in 44.1% (n = 237), the women received 2 doses or 1600 μg. Most of the women who received misoprostol (94.4%) were treated as outpatients, while 5.6% (n = 30) were admitted to hospital (data not shown in tables).

Two-thirds of the women with pregnancies of up to 12 weeks used only 1 dose of misoprostol (66%); however, this proportion decreased to 34% among those with pregnancies of 13–14 weeks and to 23% for women with pregnancies of 15–18 weeks (data not shown in tables).

Gestational age was significantly associated with the success rate, defined as the percentage of cases in which MVA was not required to complete uterine evacuation. In women with pregnancies of up to 12 weeks, the success rate was 99.1%; however, this percentage dropped to only 25.7% and 27.9% in the case of women with pregnancies of 13–14 weeks and 15–18 weeks, respectively. At the ultrasound scan performed on the 15th post-treatment day, residual uterine contents were found in fewer than 5% of the women with pregnancies of up to 12 weeks. This proportion increased to 10% of women at 13–14 weeks of pregnancy and to 14% of women with pregnancies of more than 14 weeks. However, all of these cases were clinically asymptomatic and no interventions were performed (Table 2). In addition, 7.6% of women with pregnancies of up to 12 weeks and around 3% of those with pregnancies of 13–14 weeks failed to return for follow up and are presumed to have had no complications. None of the women with pregnancies of more than 14 weeks failed to return for their follow-up visit. The differences in success rates according to gestational age were statistically significant ($P < 0.001$) (Table 2).

The most common adverse effects of misoprostol treatment were pain, evaluated as severe, in 26.6% of patients (n = 143), chills in

Table 1
The percentage of incomplete abortions treated with misoprostol in the three participating hospitals in Cotonou, Benin (2008–2012).

	CUGO		HOMEL		Ménontin		Total	
Year	No.	%	No.	%	No.	%	No.	%
2008	14/116	12.1	12/156	7.7	10/112	8.9	36/384	9.4
2009	34/243	14.0	33/186	17.7	53/230	23.0	120/659	18.2
2010	49/143	34.3	45/153	29.4	26/143	18.2	120/439	27.3
2011	52/185	28.1	50/198	25.3	28/111	25.2	130/494	26.3
2012	53/214	24.8	52/192	27.1	26/127	20.5	131/533	24.6
Total	202/901	22.4	192/885	21.7	143/723	19.8	537/2509	21.4

Abbreviations: CUGO, Obstetrics and Gynecology Clinic at the Hubert Koutoukou Maga National Teaching Hospital; HOMEL, Lagoon Mother and Child Hospital; Ménontin, Ménontin Maternity Hospital.