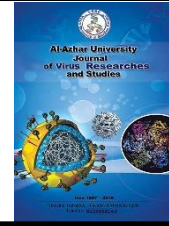




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### Clinical Audit of Management of First Trimester Missed Miscarriage at Central Aga Hospital

Mona M. Mohammed Soliman<sup>1</sup>, Azza M. Abdul-Moneim Alyamani\*<sup>1</sup> and Hala Waheed  
Abd Elhalim<sup>1</sup>

<sup>1</sup>Department Obstetrics & Gynecology, Faculty of Medicine For girls, Al-Azhar  
University, Cairo, Egypt.

\*E-mail: drazza2004@hotmail.com

#### Abstract

Early missed miscarriage represents 10% of all clinically recognized pregnancies. Introducing the best effective management for such cases is highly important for both patients and healthcare providers. To assess the management of the first trimester missed miscarriage at Central Aga Hospital and put a plan of quality improvement of this healthcare provision aiming to close the gap between the current practice and the best standards. A Criterion based clinical audit was conducted at Central Aga hospital, for one year from August 1<sup>st</sup>, 2018, to July 30<sup>th</sup>, 2019. Seventy-three cases of the first trimester missed miscarriage were studied. All the collected data were compared to ACOG (2015) and FIGO (2017) Standards. Twenty cases were managed expectantly with a 15% success rate. Sixty-three cases were managed medically by misoprostol (49 cases from the start and 14 cases after failed expectant management), with a 47.6% success rate. The duration of misoprostol treatment was lower in the successful group than the failed one with a highly statistically significant difference ( $1.3 \pm 1.21$  vs  $3.2 \pm 2.2$  days at  $P=0.001$  respectively). The vaginal or sublingual routes of misoprostol administration showed the highest rate of effectiveness (33.3% and 33.3% respectively). Thirty-three cases were managed surgically (4 cases from the start, 3 cases after failed expectant and 26 cases after failed medical) with complete evacuation. There was a gap between early missed miscarriage management at Central Aga hospital and that of the comparable standards. A needed plan of improvement was put, and re-auditing is required.

**Keywords:** Clinical audit, Management of early missed miscarriage.

#### 1. Introduction

Nearly 80% of pregnancy losses occur in the first trimester [1]. Expectant management, medical therapy, and surgical evacuation are all acceptable therapeutic options, because no approach is clearly superior, the reviewers concluded that patient preference should guide the choice

of intervention [2]. Clinical auditing is a quality improvement approach that attempts to enhance patient care and outcomes by conducting a systematic evaluation of treatment in certain place against defined criteria to offer a framework for change [3]. Therefore, this

work aimed to assess the first trimester missed miscarriage management at Central Aga Hospital, using criterion-based clinical audit, and put a plan for quality improvement of healthcare provision aiming to close the gap between current practice and the best standard.

## 2. Patients and Methods

A Criterion based observational analytical clinical audit was conducted at Central Aga hospital, during the period of one year, from August 1<sup>st</sup>, 2018, to July 30<sup>th</sup>, 2019. Seventy-three cases of the first trimester missed miscarriage were studied, data were collected from patients' files.

### 2.1 Inclusion criteria:

All cases were admitted or came to Central Aga hospital in the first-trimester miscarriage and diagnosed by Transvaginal Ultrasound (TV\US).

### 2.2 Method:

Data were collected using a specially designed sheet including detailed history taking, full examination, and investigations. Data regarding different methods of management details were also recorded.

Patients who were admitted at the period of the study were diagnosed by using two-dimension transvaginal ultrasound Siemens Acuson x150 (Korea) apparatus. Policy in Central Aga hospital for diagnosis of missed miscarriage depended on the clinical condition and documented ultrasound guidelines for transvaginal ultrasonographic diagnostic criteria for early pregnancy loss. Patients who were diagnosed as missed miscarriage underwent expectant, medical, or surgical management of missed miscarriage, without intervention from the side of the investigator.

### 2.3 Expectant management:

Patients were informed to come weekly to the clinic for follow-up for vital signs, local examination, and TV\US for two weeks. All patients were informed to attend the hospital if moderate or heavy vaginal bleeding had developed.

### 2.4 Medical management:

Misoprostol was used with different doses, routes, and durations depending on the decision of medical staff on duty and the clinical data of the patients. Medical management was considered successful if complete evacuation had occurred.

### 2.5 Surgical management:

Suction evacuation or sharp dilatation and curettage were done. All patients received post-abortive treatment: metronidazol, broad-spectrum antibiotics, and analgesics. The collected data were subjected to statistical analysis and the results were compared to the ACOG (4) and FIGO (5) guidelines.

### 2.6 Ethical approval:

Approval of the ethical committee was obtained from the Faculty of Medicine, Al-Azhar University No. of approval (20191129).

### 2.7 The statistical analysis:

Data were statistically described, Chi-square test was performed and two-sided p values less than 0.05 was considered statistically significant using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

## 3. Results

In Most of the study missed miscarriage cases (97.4 %) were diagnosed by

transvaginal ultrasound by CRL  $\geq$  7 mm and no heartbeat. Our results were in agreement with (ACOG, 2015) in the diagnoses of missed miscarriage by transvaginal ultrasound. In expectant management most cases, 17/20 (85%) failed expectant management and followed by either medical or surgical treatment. In medical treatment 26/49 (53.1%) failed and needed surgical evacuation. Only 4/73 (5.5%) of cases needed surgical treatment from the start as shown in Table .3. High

statistically significant difference between successful and failed medical management cases as regards duration of the treatment being lower in successful group as shown in Table .4. The Vaginal or sublingual routes showed the highest rate effectiveness while the oral route alone as well as Combined with sublingual route showed the lowest rate as shown in Table .5. All cases took preoperative prophylactic antibiotics and received general anesthesia as shown in Table .6.

**Table (1):** Demographic characteristics of patients participating in the study.

Socio-demographic data	Missed miscarriage (N.73)		
	Expectant N.20	Medical N.49	Surgical N.4
Age (years)			
15 -19	1 (5%)	6 (12.24%)	-
20 – 24	7 (35%)	11 (22.45%)	-
25 – 29	2 (10%)	8 (16.33%)	1 (25%)
30 - 34	4 (20%)	9 (18.37%)	1 (25%)
35 - 39	5 (25%)	12 (24.49%)	-
40 - 44	1 (5%)	3 (6.12%)	2 (50%)
Range	(18 - 40)	(17 – 42)	(31 – 42)
Mean $\pm$ SD	28.22 $\pm$ 7.04	28.8 $\pm$ 7.36	38 $\pm$ 6.08
Gravidity			
PG	3 (15%)	9 (18.37%)	1 (25%)
1 – 3	9 (45%)	22 (44.90%)	2 (50%)
>3	8 (40%)	18 (36.73%)	1 (25%)
Range	(1 – 7)	(1-6)	(1-4)
Mean $\pm$ SD	3.1 $\pm$ 1.48	3.1 $\pm$ 1.55	2.3 $\pm$ 1.53
Gestational age (weeks)			
Rang	(8-11)	(7-12)	(9-11)
Mean $\pm$ SD	9 $\pm$ 1.24	10.05 $\pm$ 1.69	10 $\pm$ 0.82
Complaint			
- Vaginal bleeding:			
• Mild	11 (55%)	41 (83.67%)	4 (100%)
• Moderate	-	8 (16.33%)	-
- No complaint (accidentally discovered at routine investigations of antenatal care)	9 (45%)	-	-
History of previous abortion			
One abortion	2 (10%)	10 (20.41%)	2 (50%)
Two abortions	1 (5%)	1(2.04%)	1 (25%)
Three abortions	1 (5%)	-	-
History of consanguinity	2 (10%)	1 (2.04%)	-
Mode of previous deliveries:			
C.S***	9 (45%)	17 (34.7%)	1(25%)
S.V.D****	5 (25%)	16 (23.65%)	2 (50%)
Both	3 (15%)	5 (10.20%)	-
History of medical disease:			
• Diabetes mellitus	-	3 (6.12%)	-
• Hypertension	1 (5%)	1 (2.04%)	-
• Both	-	1 (2.04%)	-
• Hypothyroidism	1 (5%)	-	-

SD\*standard deviation P.G\*\* primigravida, C.S\*\*\* cesarean section, S.V.D\*\*\*\* spontaneous vaginal delivery.

**Table (2):** Diagnostic Ultrasound findings of the missed miscarriage cases in the study.

Parameter	Missed miscarriage (N.73)	Study results (N.73)	Standard ACOG, 2015
Mean sac diameter (mm)	1/73 (1.37%)	One case out of 73(1.37%) was diagnosed as missed miscarriage With Mean sac diameter equal 25mm and no embryo.	Mean sac diameter 25mm or greater and no embryo.
Crown-rump length(mm) Range Mean ± SD	71/73 (97.4%) (7-50) 24.71±11.7	71cases out of 73(97.4%) were diagnosed as missed miscarriage with Crown-Rump Length of 7mm or greater and no heartbeat.	Crown Rump Length of 7mm or greater and no heartbeat.
Absence of embryo with heartbeat 2weeks or more after a scan that showed gestational sac without a yolk sac.	1/73(1.37%)	One case out of 73 (1.37%) was diagnosed as missed miscarriage with the absence of an embryo with heartbeat 2 weeks after a scan that showed a gestational sac without a yolk sac.	Absence of embryo with heartbeat 2weeks or more after a scan that showed gestational sac without a yolk sac. (Society of Radiologists in ultrasound guidelines,2012).

**Table (3):** Outcome of different types of management among the studied group.

Management	Missed miscarriage N.73	The study results
1. Expectant management:	20 (27.4%)	
*Complete evacuation		3 (15.0%)
*Failed followed by medical Treatment		14 (70.0%)
*Failed followed by surgical		3(15.0%)
2. Medical management from the start:	49 (67.1%)	
*Complete evacuation		23 (46.9%)
*Failed followed by surgical		26 (53.1%)
3. Surgical management from the start:	4 (5.5%)	4 (5.5%)

**Table (4):** Medical management in the study group (63 cases) \*\*.

Misoprostol (Misotac)	Successful (n.30)	Failed (n.33)	P* value
1-Route of administration			
Oral	2/30 (6.7%)	10/ (30.3%)	0.108
Oral+ sublingual	1/30 (3.3%)	1/33 (3.0%)	
Sublingual +vaginal	7/30 (23.3%)	5/33 (15.2%)	
Vaginal	10/30 (33.3%)	9/33 (27.3%)	
Sublingual	10/30 (33.3%)	8/33 (24.2%)	
2-Dose (total /micrograms)			
Range	(800-4400)	(600-5600)	0.877
Mean ± SD	1633.3±698.9	1963.6±1363.3	
3-Duration (days)			
Range	(0.3***-6.0)	(1.0-9.0)	0.001
Mean ± SD	1.3±1.21	3.2±2.2	

\* P Value significant at  $P < 0.05$ , \*\* (63 cases); 49 cases were administrated on medical treatment from the start and the other 14 cases were failed from expectant then followed by medical treatment. 0.3 days, \*\*\* equal 8 hours.

**Table (5):** Medical management among the study group compared to the standard (ACOG, 2015 and FIGO, 2017).

Item	Successful (N.30)	The study results	Standard
Premedical antibiotics	11/30 (36.7%)	11/30 (36.7%) of cases received premedial antibiotics in the form of 1.5 gm Unictam.	The benefit of antibiotics prophylaxis is unknown. (ACOG,2015)
Misoprostol (Misotac)			
1-Route of administration			
-oral	2/30 (6.7%)	Two thirds of the cases received vaginal or sublingual misoprostol which agreed with the standard	vaginal Sublingual (FIGO,2017)
-Oral+sublingual	1/30 (3.3%)		
-Sublingual +vaginal	7/30 (23.3%)		
-vaginal	10/30 (33.3%)		
-Sublingual	10/30 (33.3%)		
2- Total dose of Misoprostol (total /mcg)			
Range	(800-4400)	The cases received high total dose of Misoprostol reaching up to 4400 micrograms. Because the patients took Misoprostol during their hospitalization staying till evacuation had occurred.	(800-1600) (ACOG,2015)
Mean ± SD	1633.3±698.9		
3-Frequency of dose administration (times)			
		The high-frequency rate for dose administration reached up to 8 times. Because we give patients the dose according to the order of the consultants on the day.	
Range	(1-8)		(1-2) (FIGO,2017)

**Table (6):** Surgical management among the study group compared to the standard (ACOG, 2015 and FIGO, 2017).

Items	Surgical management (N.33) *	Study results	Standards
Preoperative antibiotics	33/33 (100%)	All cases received 1-hour preoperative antibiotics in form of single dose of Cefotax 1gm vial or Unictam 1.5 gm vial.	Single 200mg dose of Doxycycline 1hour preoperative to prevent postoperative infection. (ACOG,2015)
Preoperative misoprostol *400mcg sublingual 1hour before operation *400 mcg vaginal 3hours before operation	6/33 (18.2%) 2/33 (6%)	8/33 (24.2%) cases were prepared by misoprostol preoperatively. Six of them took 400mcg sublingual 1hour before operation while two took 400 mcg vaginal 3hours before operation	400 mcg sublingual 1hour before operation or 400 mcg per-vaginal 3hours before operation (FIGO,2017)
Type of anesthesia General Local Spinal	31/33 (94.0%) 1/33 (3%) 1/33 (3%)	Most cases received general anesthesia.	Local or general anesthesia (ACOG,2015).
Mode of termination			
Suction& Curettage	12/33 (36.4 %)	Most cases had sharp curettage 21/33 (63.6%).	The use of suction curettage is superior to the use of sharp Curettage alone. (ACOG,2015).
Sharp Curettage	21/33 (63.6%)		
Post-operative treatment	33\33 (100%) cases received postoperative treatment	All cases received post-operative treatment in the form of oral Flagyl, broad-spectrum antibiotics (Ciprofar or Ampicillin) and Analgesics	No need for postoperative treatment. (ACOG,2015)
The Deficit in Hb level between pre and post suction curettage (gm/dl) Mean	1.1±0.4	The mean hemoglobin deficit between pre and post suction curettage was 1.1gm/dl	Women randomized to the misoprostol group were significantly more likely to have a decrease in their hemoglobin levels greater than or equal to 3g/dl than women in the vacuum aspiration group. (ACOG,2015)

\* 33 cases; 4 cases surgical from the start, 3 cases after failed expectant, and 26 cases after failed medical.

#### 4. Discussion

This study aimed to assess the management of the first trimester missed miscarriage at Central Aga Hospital by using criterion-based clinical audit, and put a plan of improvement of the quality of this medical

care, aiming to close the gap between current practice and the best standard Regarding demographic characteristics of participants, the percentage of patients age who were above 40 years in the expectant, medical, and surgical was 6 \ 73 (8.23%) (Table1). This is in contrary to ACOG [4]

as they reported that the frequency of cases increases by 80% at the age of 45 years. This could be explained by the small sample size of the current study. However, our results agreed with those of Gleicher et al. [6] who found more substantial increases in missed miscarriage after age 35 years (23 out of 73, 31.5%) of our cases.

The current study results also revealed that there were 3 cases (4.1%) that had a positive history of consanguinity. These results were different from those of Abd Elsalam et al. [7] who demonstrated that chromosomal abnormalities are implicated in approximately 50% of all spontaneous miscarriage.

Treatment of missed miscarriage options includes expectant management, medical treatment, or surgical evacuation. In the cases who were admitted during the study period, patients were counseled about the preferred type of management, 20 of them preferred expectant management. In this study, expectant management was applied to 20\73 (27.4%) of women. With this approach most of the cases were failed, while complete spontaneous evacuation of the products of conception had occurred in only 3\ 20 cases (15%) (Table 3).

On the other hand, our medical management from the start by using misoprostol was carried on 49 cases (67.1%) with a success rate of 46.9% (Table 3). This was in agreement with Chen & Creinin [8] who stated that the success rate of medical evacuation varies from 25% up to 97% for oral, sublingual, or vaginal misoprostol in different studies. These variations between studies probably reflect the different misoprostol regimens used and the route of administration.

The present study results in the medical management group showed that there was a high statistically significant difference between successful and failed medical management cases as regards the duration of the treatment being lower in the successful group (at P-value 0.001) (Table 4).

These results nearly with those achieved by Neilson et al., [9] who stated that medical

management of missed miscarriage has become an established and cost-effective alternative to the classical surgical evacuation of the uterus with a success rate as high as 80 – 90%.

Comparing medical management among the study group in Central Aga Hospital to the standard; Only 11\73 cases received premedical antibiotics against ACOG [4] which stated that the benefit of antibiotics, prophylaxis is unknown.

Regarding, route of administration of Misoprostol, the current study results revealed that two-thirds of the cases 20\30 (66.66%) received vaginal or sublingual Misoprostol which nearly agreed with the (FIGO) [5] standards and study which studied different administration routes of Misoprostol and suggested only vaginal or sublingual routes for its administration.

Although no option of treatment of missed miscarriage is clearly superior to others, surgical evacuation is commonly preferred by doctors from the start. In Central Aga Hospital 33\73 cases (45.2%) were managed surgically with complete evacuation. Only 8 cases were prepared by Misoprostol preoperatively with the same dose recommended by FIGO [5] (Table 6).

The study results were nearly similar to those of Musallam et al. [10] study, a total of 43 cases were treated by surgical management, 41 cases of them were treated after the failure of medical management. The majority of cases received antibiotic prophylaxis after surgical management.

In the present study results, most cases received general anesthesia in contrast to ACOG [4] which recommended local or general anesthesia. This may be due to a lack of experience in using local anesthesia at Central Aga Hospital.

Regarding the method of evacuation, most cases in the present study were evacuated using sharp curettage (63.6%), which was against ACOG [4] recommendations that the use of suction curettage is superior to the use of sharp curettage alone. This is because suction curettage in Central Aga hospital is restricted to cases with previous CS and incomplete abortion.

All cases in the present study received post-operative treatment in the form of oral Metronidazol, broad-spectrum antibiotics, and analgesics as routine treatment for fear of post-abortive infection (Table 6), this differs from that stated by ACOG [4] standards that no need for post-operative treatment.

## 5. Conclusion

1. Transvaginal Ultrasound is the gold standard for accurate diagnosis of missed miscarriage.
2. Sublingual or vaginal routes of Misoprostol administration are highly effective with low duration.
3. Preoperative antibiotics are advisable to prevent post-abortive infection.

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