

## Impact of the introduction of the active follow-up care of the third stage of childbirth in the prevention of delivery hemorrhage in the obstetrical gynecology department

Jeremie Pagnol Bille Bonga <sup>1,\*</sup>, Michele Corneille Matchim Kamdem <sup>2</sup>, Leila Sandra Nnanga <sup>2</sup>, Ghislain François Eyimi Abessolo <sup>3</sup> and Marcellin Ndoe Guiaro <sup>2,3,\*</sup>

<sup>1</sup> Gamal Abdel Nasser University, Conakry, Guinea.

<sup>2</sup> Institute of Medical Research and Medicinal Plants Studies (IMPM), Ministry of Scientific Research and Innovation, Yaounde, Cameroon.

<sup>3</sup> East Regional Delegation of Public Health, Bertoua, Cameroon.

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### Abstract

**Background:** The majority of pregnancies and births proceed without complications. However, all pregnancies present risks of complications that could endanger the maternal prognosis. One of the most serious of these complications is the bleeding during delivery. It's often unpredictable nature, when it occurs, involves an urgent obstetric situation which requires early diagnosis and rapid and effective follow-up. The general objective of this study was to assess the impact of the introduction of the active follow-up care of the third phase of childbirth in the prevention of bleeding during delivery with our place of study, the obstetrical gynecology department of Kindia regional hospital (Konacri Guinea), with the aim of optimizing the follow-up care of pregnant women during their childbirth.

**Methodology:** We carried out a case-control study with both retrospective and prospective data collection on the records of participants with cases of hemorrhage during delivery in the gynecology department of the Kindia regional hospital. Retrospective data collection covered a period of 25 months before the active follow-up care of the third stage of childbirth and concerned the control group of study participants, while the one of prospective data covered a period of 19 months after the introduction of the active follow-up care of the third stage of childbirth from the 1<sup>st</sup> January 2019 to 30<sup>th</sup> September 2020 and concerned the cases group. The criteria for matching these two groups of study participants were the diagnosis and the follow-up of the delivery hemorrhage.

**Results:** During our study period in the gynecology department of the Kindia regional hospital, we identified 223 cases of delivery hemorrhage out of 2198 deliveries before the period of introduction of the active follow-up care of the third stage. This represents an incidence of 10.14%, compared to 73 cases of delivery hemorrhage out of 2714 deliveries during the period of the active follow-up care of the third stage. For an incidence of 2.68%. We found that the hemorrhages during delivery did not spare any age group and were observed for all parities. There were common reasons for admission before and after the integration of the active follow-up care of the third stage of childbirth namely vulvar hemorrhage and physical asthenia, which were reflected in the clinical picture of all cases bleeding from the issue. In addition, headaches, dizziness, and thirst were found, but in different proportions and significantly less frequent since the introduction of the active follow-up care of the third stage of childbirth. This sign were in this context the consequence of the state of shock with respective frequencies of 46.63% and 28.76% before and after the introduction of the active follow-up care of the third stage of childbirth and anemia was present in all cases of delivery hemorrhage.

\* Corresponding author: Marcellin Ndoe Guiaro

Institute of Medical Research and Medicinal Plants Studies (IMPM), Ministry of Scientific Research and Innovation, Yaounde, Cameroon.

**Conclusion:** The introduction of active follow-up care of the third stage of childbirth has reduced the frequency of delivery hemorrhages and may therefore help to reduce maternal morbidity and mortality.

**Keywords:** Delivery Hemorrhage; Childbirth; Pregnancy; Obstetrical Gynecology

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## 1. Introduction

Delivery hemorrhages are losses of blood having their source in the placental insertion zone, occurring at the time of delivery or within 24 hours after childbirth, abnormal in their abundance (more than 500 ml ) and also by their effects on the general condition of the parturient [1]. The majority of pregnancies and births proceed without complications. However, all pregnancies present risks of complications that could endanger the maternal prognosis. One of the most formidable of these complications is the delivery hemorrhage. It's often unpredictable nature, when it occurs, it involves an urgent obstetric situation which requires early diagnosis and rapid and effective intervention [2]. Severe delivery hemorrhage, that is to say greater than 1000ml, has a significant impact on the general maternal condition and requires emergency treatment. Otherwise a defibrination syndrome sets in, exposing the parturient to life-threatening risk [3]. However, better knowledge of risk factors, prevention of delivery hemorrhages and early intervention by the obstetrical team can limit the risk of death from hemorrhagic shock [2]. Three types of measures can be taken in this situation: preventive, diagnostic and therapeutic [4]. Even if some circumstances are favorable, the accident is largely unpredictable; this is why the third phase of childbirth must be carried out with such rigor to avoid this accident, which can sometimes be iatrogenic. Hence the introduction of the active follow-up care of the third stage of childbirth, which is an obstetrical practice that aims to facilitate the expulsion of the placenta and prevent bleeding during delivery.

The active follow-up care of the third stage of childbirth consists of three main steps, namely: the intramuscular administration of an uterotonic drug, the controlled traction of the umbilical cord and the uterine massage after delivery. A curative intervention must be applied within the strictest timeframe, using oxytocics, possibly prostaglandins, sometimes mechanical means and more rarely resuscitation and sometimes blood transfusion [5].

Today, although progress is being made in its follow-up care, the delivery hemorrhage remains a leading cause of maternal morbidity and mortality [2]. Severe anemia, accidents and complications of blood transfusion, hemodynamic shock, acquired coagulopathies, hemostatic hysterectomy [6]. On the other hand, each year, 14 million cases of delivery hemorrhage occur and are responsible for around 30% of maternal deaths worldwide and nearly 60% of deaths in some countries [7]. It is a formidable complication of childbirth. In France, it concerns 5% of women, and is the leading cause of maternal mortality during pregnancy [8]. It is responsible for around 15%-20% of maternal deaths [9]. In the USA, maternal mortality linked to delivery hemorrhage is 13% [2]. In developing countries, where the maternal mortality rate is between 5% and 10%, the delivery hemorrhage is by far the leading cause of death [9]. In Africa the incidence of delivery hemorrhages varies from a country to another country. It is 4.67% in the Central African Republic [2]; 1% in Cameroon [9]; 1.28% in the Democratic Republic of Congo [10]; 31.5% in Tunisia [2]; 2.23% in Morocco [11]; 1.36% in Lome in TOGO [12]; 47.82% in Benin [13]; 13% in MALI [14]. In Guinea, per 100.000 live births, 980 mothers lose their lives at the same time and 15% of these deaths are due to pre- and post-partum hemorrhage and anemia [7]. Here the incidence of the delivery hemorrhage varies from 6.4% to 54.5% depending on the hospital structures.

Despite the implementation of a National Safe Motherhood Program by the Ministry of Health and Public Hygiene of Guinea, the frequency of the delivery hemorrhage and its maternal complications remains considerable, and the difficulties of taking in charge no less important. Hence the interest of the present study carried out at the Regional Hospital of Kindia with the general objective of highlighting the impact of the introduction of the active follow-up care of the third stage of childbirth in the prevention of the delivery hemorrhage in the obstetrical department of gynecology. Its specific objectives were to determine the incidence of delivery hemorrhages in the obstetrical department of gynecology from this hospital, to describe the epidemiological profile of the woman likely to have delivery hemorrhage in the obstetrical department of gynecology, to describe the clinical aspects of the delivery hemorrhage from the obstetrical department of gynecology and to compare the results obtained from treatment before and during the introduction of the active follow-up care of the third stage of childbirth in the obstetrical department of gynecology.

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## 2. Material and methods

### 2.1. Type of study, sampling and target population

We conducted a case-control study with both retrospective and prospective data collection on the records of parturients with cases of delivery hemorrhages in the gynecology department of the Kindia regional hospital. Retrospective data

collection covered a period of 25 months before the active follow-up care of the third stage of childbirth and concerned the control group of study participants, while the one of prospective data covered a period of 19 months after the introduction of the active follow-up care of the third stage of childbirth from 1<sup>st</sup> January 2019 to 30<sup>th</sup> September 2020 and concerned the group of cases. The criteria for matching these two groups of study participants were the diagnosis and the follow-up care of delivery Hemorrhage.

## 2.2. Inclusion and exclusion criteria

We included in our study only the files of participants presenting cases of delivery hemorrhage, supported in our place of study and having given their agreement for the participation in the study by the signature of an informed consent form. Participants excluded from the study were those with other postpartum hemorrhages.

## 2.3. Data collection

We used a pre-established questionnaire; we identified the 2 groups of study participants (cases and controls) by listing the files of participants with delivery hemorrhage in our study place. The data collected was focused on the incidence of delivery hemorrhages in our study place, on the epidemiological profile of women susceptible to delivery hemorrhage, on the clinical aspects of the delivery hemorrhage and also on the behavior held in front of a delivery hemorrhage (HDD).

## 2.4. Statistical analysis

The data collected expressed in numbers and percentages were analyzed using the Epi info software and the chi-square test of independence was used to compare the different percentages obtained in the two groups of study participants (cases and controls) with a significance threshold set at 5%.

## 2.5. Ethical Consideration

We obtained authorization from the national ethics committee of Guinea and also those from the university and hospital administration of Kindia, which served as a springboard for the success of our study. In turn, study participants were verbally informed of its advantages and disadvantages before to sign the informed consent and their anonymity was maintained throughout the study period and was not published.

## 3. Results

### 3.1. Incidence of delivery hemorrhage

The incidence of delivery hemorrhage cases was very low after the introduction of the active follow-up care of the third stage of childbirth (Table 1).

**Table 1** Distribution of participants according to the presence of delivery hemorrhages before and after the introduction of the active follow-up care of the third stage of childbirth

Childbirth	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
With delivery hemorrhage	223	10.15	73	2.7	0.001
Without delivery hemorrhage	1975	89.85	2641	97.3	0.05
Total	2198	100	2714	100	0.03

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

### 3.2. Epidemiological and socio-demographic profile of the participants

#### 3.2.1. Age

The average age of participants (Cases and Controls) was  $29 \pm 10.25$  years with age ranging from 15 years to 43 years. Delivery hemorrhage affected participants at all ages and the number of delivery hemorrhage cases was reduced during the period of the active follow-up care of the third stage of childbirth (Table 2).

**Table 2** Distribution of participants according to age groups

Age group (In years)	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
15-19	53	23.76	17	23.29	0.03
20-24	33	14.8	18	24.66	0.05
25-29	45	20.18	15	20.54	0.01
30-34	41	18.39	10	13.7	0.01
≥ 35	51	22.87	13	17.81	0.01
Total	223	100	73	100	0.001

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

### 3.2.2. Parity

The frequency of delivery hemorrhage decreased as the parity increased. It was higher among primiparous before and after the introduction of the active follow-up care of the third stage of childbirth with frequencies of 30.5% and 34.25%, respectively. The number of delivery hemorrhage cases was reduced during the period of the introduction of the active follow-up care of the third stage of childbirth (Table 3).

**Table 3** Distribution of participants according to their parity

Parity	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
Primiparous	68	30.5	25	34.25	0.03
Pauciparous	47	21.07	24	32.87	0.01
Multiparous	53	23.76	14	19.18	0.01
Large Multiparous	57	24.67	10	13.7	0.01
Total	223	100	73	100	0.001

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

### 3.2.3. Marital status

For both study periods, the married women were the most affected by the delivery hemorrhage with the frequencies of 92.37% and 98.63% respectively before and after the introduction of the active follow-up care of the third stage of childbirth (Table 4).

**Table 4** Distribution of participants according to their marital status

Marital status	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
Married	206	92.37	72	98.63	0.05
Single	17	7.63	1	1.34	0.01
Total	223	100	73	100	0.001

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

### 3.3. Clinical aspects of the delivery hemorrhage

#### 3.3.1. Admission mode to the gynecology department

For both study periods, the majority of cases of delivery hemorrhages came from women who gave birth at home with frequencies of 93.72% and 95.89% respectively. The number of cases of delivery hemorrhages was reduced during the period of the introduction of the active follow-up care of the third stage of childbirth (Table 5).

**Table 5** Distribution of participants according to their admission mode to the gynecology department

Admission mode	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
Referred	14	6.28	3	4.11	0.03
Home	209	93.72	70	95.89	0.01
Total	223	100	73	100	0.001

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

#### 3.3.2. Reason for admission

We found that vulvar hemorrhage and physical asthenia were the most common reason for admission seen in all of our participants during both study periods (Table 6).

**Table 6** Distribution of participants according to the reason for admission

reason for admission	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
Vulvar hemorrhage	223	100	73	100	0.001
Headache	104	46.63	21	28.76	0.01
Physical asthenia	223	100	73	100	0.001
Dizziness	104	46.63	21	28.76	0.01
Thirst	104	46.63	21	28.76	0.01

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

#### 3.3.3. Etiology

Placental retention was the most common etiology during the two study periods in our participants, but with a reduced number during the period of the introduction of the active follow-up care of the third stage of childbirth (Table 7).

**Table 7** Distribution of participants according to etiologies of the delivery hemorrhage

Etiology	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
Uterine atony	15	6.73	4	5.48	0.01
Placental Retention	208	93.27	69	94.52	0.01
Total	223	100	73	100	0.001

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

#### 3.3.4. Clinical forms

Anemia was the most common clinical form seen in all of our participants during both study periods (Table 8).

**Table 8** Distribution of participants according to clinical forms

Clinical forms	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
State of shock	104	46.63	21	28.76	0.01
Anemia	223	100	73	100	0.001

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

### 3.4. Management of the delivery hemorrhage

#### 3.4.1. Types of interventions (Physical means, Resuscitation, Uterine evacuation technique, Use of uterotonics)

The intervention by blood transfusion was markedly reduced during the period of the introduction of the active follow-up care of the third stage of childbirth (Table 9).

**Table 9** Distribution of participants according to the type of intervention used in the management of the delivery hemorrhage

Type of intervention	Before the AFCTSC		After the AFCTSC		P.value
	Number	Percentages (%)	Number	Percentages (%)	
Uterine massage	223	100	73	100	0.001
Intake of the venous line	223	100	73	100	0.001
Blood transfusion	104	46.63	21	28.76	0.01
Artificial delivery	94	42.15	00	00	/
Uterine revision	00	00	9	12,32	/
Oxytocin	223	100	73	100	0.001

AFCTSC= Active Follow-up care of the Third Stage of Childbirth

## 4. Discussion

### 4.1. The incidence of cases of delivery hemorrhage

The period preceding the introduction of the active follow-up care of the third stage of Childbirth from our study at the department of gynecology from the Regional Hospital of Kindia reported 223 cases of delivery hemorrhage out of 2198 deliveries, that is an incidence of 10.14% against 73 cases of delivery hemorrhage out of 2714 deliveries after the introduction of the active follow-up care of the third stage of childbirth, that is an incidence of 2.68% (P = 0.001) (Table 1). The most rational cause of this reduction is the introduction of the active follow-up care of the third stage of childbirth in the minimum package of activities from the gynecology department of the Kindia regional hospital. In fact, this activity was initiated in all gynecology departments of hospitals in the country by the Ministry of Health and Public Hygiene as a method to reduce early postpartum hemorrhages, including delivery hemorrhage, this being one of the top three preventable causes of maternal mortality. Despite its considerable drop observed from one period to another, the incidence of our study is still higher than those found in other studies done in Guinea like those made by Diallo and Traore in their studies on the delivery hemorrhage in Guinea, which found respective incidences of 0.86% and 2.25% at the University Hospital Center (CHU) of Donka respectively in the years 2005 and 2002 [2,15].

### 4.2. Age

In the two study populations corresponding respectively to the periods before and after the integration of the active follow-up care of the third stage of childbirth, the average age of participants was  $29 \pm 10.25$  years with ages ranging from 15 years old to 43 years old. The two periods were therefore statistically comparable because the two populations had identical characteristics. It emerges from the study that delivery hemorrhages do not spare any age group and therefore, age would not be a discriminatory factor of the beneficial effects from the introduction of the active management of the third stage of the childbirth at the hospital gynecology department. The age group of 15 to 29 years

was the most represented in the two periods from our study with respective frequencies of 58.74% and 68.5% (Table 2). Our frequency was significantly higher than the one found in the study carried out by Guissou in Burkina Faso in 2008 on the active follow-up care of the third stage of Childbirth which reported a frequency of 60% for this age group [16] and also higher than the one of 45.9% obtained by Camara in Mali in 2005 on the same topic [17].

#### **4.3. Parity**

Based on the results observed over the two study periods, delivery hemorrhage was observed in all parities. But its frequency would be higher among primiparous where it was 30.5% and 34.25% respectively before and after the introduction of active follow-up care of the third stage of childbirth (Table 3). However, we found that, during the period of the integration of the active follow-up of the third stage of childbirth in our study site, the frequency of delivery hemorrhage decreased as parity increased. Therefore, we deduced that parity would not be a discriminatory factor of the beneficial effects of the introduction of the active follow-up of the third stage of childbirth in the gynecology department of hospitals. Our observation was similar to the one made by Derbal in his study in Tunisia in 1993 on delivery hemorrhage, which reported a frequency of 38.6% among primiparous mothers, thus occupying the first position with regard to the occurrence of delivery hemorrhages [2], while Diallo in a similar study in Guinea in 2005 reported a contradictory finding to ours ranking the multiparous mothers in the first rank of delivery hemorrhages with a frequency of 60.26% [2]. This finding could be explained by the fact that they were the study participants who are very sexually active, who did not regularly attend antenatal clinics, who cooperated less during childbirth and who are often under-informed about the pregnancy and its normal course.

#### **4.4. Marital status**

We noted that marital status was not a factor that discriminated against the beneficial effects of the introduction of the active follow-up of the third stage of childbirth in the gynecology department of hospitals. Married participants were the most affected by delivery hemorrhages with the respective frequencies of 92.37% and 98.63% before and after the introduction of the active follow-up care of the third stage of childbirth (Table 4). This observation was similar to those made in the studies of CAMARA in 2005 in Mali and of GUISSOU in 2008 in Burkina Fasso on the same topic and for which also the married were the most represented with respective frequencies of 85.5%. [15] and 73% [9].

#### **4.5. Admission mode**

We noted that the admission mode was not a factor that discriminated against the beneficial effects of the introduction of the active follow-up of the third stage of childbirth. The majority of cases of delivery hemorrhages came from women who gave birth at home with respective frequencies of 93.72% and 95.89% (Table 5). This observation was similar to the one made by Loua in Guinea in 2004, in his study where women who gave birth at home were also the most affected by delivery hemorrhages with a frequency of 50% [18]. This finding could be explained by a lack of adequate care by qualified people at home and consequently by poor management of the third phase of childbirth.

#### **4.6. Reason for admission**

The two study periods had common reasons for admission, namely vulvar hemorrhage and asthenia, which were found in all cases of delivery hemorrhage. In addition to these clinical signs, headache, dizziness, and thirst were also found, but in different proportions and significantly less frequent since the introduction of the active follow-up care of the third phase of childbirth (Table 6). These signs were in this context the consequence of the state of shock which was more frequent before the introduction of the active follow-up care of the third stage of childbirth, but reduced during the period of its application because of the improvement the skills of providers after training on this topic and its proper application during childbirth. The presence of hemorrhagic shock in the two samples, although at different frequencies and respectively of 46.63% and 28.76% (Table 6), could be the consequence of the delivery modalities (unassisted deliveries) but also the delay of the care in the structure (third delay) and sometimes the inadequacy of the care. These frequencies of shock in our two study periods were still higher than the one of 20% found by GOFFINET in 1997 in France during its study on delivery hemorrhages [6].

#### **4.7. Etiology**

With the respective frequencies of 93.27% and 94.52% before and after the introduction of the active follow-up care of the third phase of childbirth, the placental retention was the main etiology of delivery hemorrhage. As a result, it would not be a factor that discriminates against the beneficial effects of the introduction of active follow-up care of the third stage of childbirth in the gynecology department of hospitals because it was noted in similar proportions with or without active follow-up care of the third phase of childbirth (Table 7). Our observation was similar to those made by Diallo, Loua and Traoré in their studies for which also placental retention would be the first cause of delivery

hemorrhages in the gynecology department of hospitals with respective frequencies of 56.6%, 53.84% and 72.14% [2, 19,15]. Our frequencies and findings were also close from the one of DIALLO, with a frequency of 56.60% in his Doctoral Thesis in Medicine in Guinea, who ranked the placental retention as the leading cause of delivery hemorrhage [2]. The study of LOUA, reported also the same idea for which the placental retention was the leading cause of delivery hemorrhage with a frequency of 53.84% at the ACG hospital in Fria [19]. TRAORE also, in his Doctoral Thesis in Medicine in 2002, obtained a frequency of 72.14% [15]. On the other hand, Goffinet in his study on the same topic, classified uterine inertia as the primary cause of delivery hemorrhage with a predominant frequency of 59% [6].

#### **4.8. Clinical forms**

Anemia followed by the state of shock were the most common clinical forms found in all cases of postpartum bleeding before and after the introduction of the active follow-up care of the third stage of delivery of childbirth (Table 8). We noted a significant regression of state of shock among the clinical manifestations of delivery bleeding after the integration of the active follow-up care of the third stage of delivery of childbirth into the practice of delivery at the study site. This integration has therefore resulted in improved management of bleeding by providers after their training in the active follow-up care of the third stage of childbirth. As a result, the reduction of state of shock is a witness to the good application of this service during childbirth. Nevertheless, even after the implementation of the active follow-up care of the third stage of childbirth in our study, the frequency of 28.76% of cases of anemia found was still higher than the one of 20% found by Goffinet. in his study [6].

#### **4.9. Management of the delivery hemorrhage**

The management carried out included several components. But whether before or after the introduction of active follow-up care of the third stage of childbirth, filling solutes, antianemics, vulvar hygiene and monitoring of maternal vital parameters were systematically part of the components of the treatment. Paraclinical examinations were also carried out systematically in order to anticipate possible surgical management. However, after the introduction of active follow-up care of the third stage of childbirth, this common conduct was supplemented by uterine massage and administration of utero tonics. We have also had recourse to surgical means for some cases. The main utero tonic used here was Oxytocin because it is better tolerated by the patients.

With respective frequencies of 46.63% and 28% before and after the introduction of the active follow-up care of the third stage of childbirth, a significant decrease in the need for blood transfusion was noted after the introduction of the active follow-up care of the third stage of childbirth (Table 9). This decline could be explained by the improvement in the management of bleeding by providers after their training on the active follow-up care of the third stage of childbirth. Our observation was similar to the one made by Mc Cormick in his study on the same topic in Zambia in 2002, in which the introduction of the active follow-up care of the third stage of childbirth reduced the need for blood transfusion in his patients by 75% [21].

In short, we have noted with the integration of the active follow-up care of the third stage of childbirth, a significant improvement in the prevention of delivery hemorrhage and also in their management. The most significant benefits of this active follow-up care of the third stage of childbirth have been the significant reduction of hemorrhagic shock states and the need for blood transfusion.

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### **5. Conclusion**

Our study on the need to introduce the active follow-up care of the third stage of childbirth in the prevention of delivery hemorrhage at the Obstetrics Gynecology Department of the Kindia Regional Hospital reported 223 cases of this issue against 73 cases respectively before and after its introduction. The main etiology was the placental retention with 208 (93.27%) cases among the 223 cases of delivery hemorrhage before the introduction of the active follow-up of the third stage of childbirth against 69 (94.27%) cases of the placental retention for 73 cases after its introduction. The uterine massages, the para-clinical examinations, the administration of fluids were systematically done since the introduction of the active follow-up care of the third stage of childbirth. The administration of macromolecules was also systematically done to restore blood volume although it was contraindicated because the only best way being the use of physiological serums such as Ringer Lactate or Salted Serum. It appears that the active follow-up care of the third stage of childbirth reduces the risk and frequency of delivery hemorrhages and the need for blood transfusion. It could therefore help to reduce the maternal morbidity and mortality. It should absolutely be part of the minimum package of activities of all health facilities with a delivery room, and natural delivery withdrawn from hospital practices. The decrease in the frequency of severe bleeding during delivery goes hand in hand with the one of blood transfusion (46.63% before the introduction of the active follow-up care of the third stage of childbirth and 28.76% after its introduction), in countries where the risk of transfusion is not zero.



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## Compliance with ethical standards

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### *Disclosure of conflict of interest*

No conflict of interest. All authors contributed to the designing, preparation, editing, and final review of the manuscript.

### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

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