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## Gynecology & Obstetrics

Post Partum Haemorrhage

Angular Pregnancy a Case Report

Highlights

Co-Attached Cervical Shutter

Incarceration of Gravid Uterus

Discovering Thoughts, Inventing Future

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## Fetomaternal Hemorrhage - A Mystery Entity

By Maria Zormpa & Dr. Alfred Schleiss

**Abstract-** Fetomaternal hemorrhage is a well - recognised cause of neonatal morbidity. The diagnosis is not easy to make as the clinical symptoms if present, can be very subtle. There are diagnostic tests, as the rosette screen and Kleihauer-Betke test that can confirm the clinical suspicion and typical prenatal ultrasound signs and pathologic allaboratory results at delivery that confirm the underlying pathophysiology of the condition.

We have gone through the upto date literature and present the latest findings on fetomaternal hemorrhage. However, more studies need to be carried out to shed light to other risk factors, clinical and laboratory data associated with the disease, to decrease the fetal and perinatal morbidity and mortality.

**Keywords:** *fetomaternal transfusion, decreased fetal movements, hydropsfetalis, anemia, congestive heart failure.*

**GJMR-E Classification:** NLMC Code: WP 400



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# Fetomaternal Hemorrhage - A Mystery Entity

Maria Zormpa <sup>α</sup> & Dr. Alfred Schleiss <sup>σ</sup>

**Abstract-** Fetomaternal hemorrhage is a well - recognised cause of neonatal morbidity. The diagnosis is not easy to make as the clinical symptoms if present, can be very subtle. There are diagnostic tests, as the rosette screen and Kleihauer-Betke test that can confirm the clinical suspicion and typical prenatal ultrasound signs and pathologic allaboratory results at delivery that confirm the underlying pathophysiology of the condition.

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## 1. INTRODUCTION

The entrance of small quantity of fetal red cells into the maternal circulation during or before delivery is commonplace in all pregnancies. However, a blood loss of more than half of fetal blood volume is rare and can potentially lead to severe neonatal anemia and death up to 0.04% of all births<sup>(1,2)</sup>. Usually the cause is idiopathic and happens in low-risk late pregnancies<sup>(3,4)</sup>.

Fetomaternal hemorrhage can take place early in pregnancy because of disorders of the placental circulation. About half of mothers have detectable fetal red cells in their circulation of a very small amount<sup>(5)</sup>. Volumes in the range of 10-150 ml can be associated with FMH<sup>(6,7)</sup>. Amount exceeding 150 ml happens in a very small number of pregnancies and the severity of FMH can be assessed by the quantity of fetal cells in the maternal circulation<sup>(8)</sup>.

Known incipitating factors of fetomaternal hemorrhage include placental abruption, vasa previa, amniocentesis, chorionic villous sampling, external cephalic version, choriocarcinoma<sup>(8)</sup>. In addition, Rhesus alloimmunization has been identified as a possible cause of fetomaternal hemorrhage<sup>(9)</sup>. In that case, Rhesus + fetal cells sensitize Rhesus - maternal cells resulting in alloantibody production. This in turn can lead to hemolytic disease of the newborn (HDN)<sup>(10)</sup>. The rates of such complications are very low due to Rhesus screening and immunoprophylaxis. However in up to 82% of cases of fetomaternal hemorrhage no causative agent can be identified<sup>(11)</sup>.

There are specialised tests that can confirm the presence of fetomaternal bleeding. The rosette screen can detect small quantities of fetal blood in the maternal circulation and the Kleihauer-Betke test remains the method of choice that can confirm the diagnosis and quantify the amount of fetal cells<sup>(12,13,14)</sup>. Moreover flow-cytometry can also assist in the detection of fetal cells but has no increased sensitivity in comparison to KB<sup>(15)</sup>. In early pregnancy a sensitive marker supporting FMH is increased alfa fetoprotein (AFP). Later on, the diagnosis of FMH can be supported by both increased AFP and a positive Kleihauer-Betke test<sup>(16)</sup>.

The clinical picture can vary greatly. Fetomaternal hemorrhage can manifest as decreased fetal movements without an association with abdominal injury, pain or bleeding<sup>(17)</sup>. Abnormal CTG tracings can be discovered accidentally with decreased variability, variable or late decelerations<sup>(18,19)</sup>. Ultrasound findings include intraventricular hemorrhage, pleural and pericardial effusion and ascites<sup>(20,21)</sup> (Fig. 1, 2 & 3).

The child can suffer from severe respiratory depression and hepatomegaly or subcutaneous edema as a consequence of congestive heart failure<sup>(22,23,24)</sup>. Additionally, possible complications include neurological sequelae, for example spastic cerebral palsy and stillbirth<sup>(25,26)</sup>. The laboratory results at delivery may include increased reticulocyte number suggestive of chronic blood loss, deranged coagulation and liver enzymes and hematuria<sup>(27)</sup> (Table 1).

Table 1: Laboratory Results

Parameter	Value	Normal Range
Hemoglobin (Cord Blood) g/dl	3.4	16.8
Reticulocytes (%)	8.6	3 - 7
Platelets 10*9/L	105	290
Prothrombin Time Sec	38	10 - 12.4
APTT Sec	60	30 - 55
INR	3.20	0.9 - 1.07
Fibrinogen g/l	0.8	1.6 - 3.5
ALAT IU/L	308	0 - 30
ASAT IU/L	1534	0 - 30
Albumin g/l	14	27 - 43
Protein g/l	24	45 - 72

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The management of fetomaternal hemorrhage can also be complicated. In early pregnancy intrauterine transfusion may be attempted to correct the anemia but in cases of continuous bleeding, repeat transfusions or delivery may be indicated<sup>(28)</sup>.

Although massive fetomaternal hemorrhage is a rare condition, it is possibly under diagnosed because of the lack of clinical suspicion<sup>(10)</sup>. With fetomaternal hemorrhage being an etiology of serious fetal morbidity and mortality, further research is essential for avoiding significant complications.

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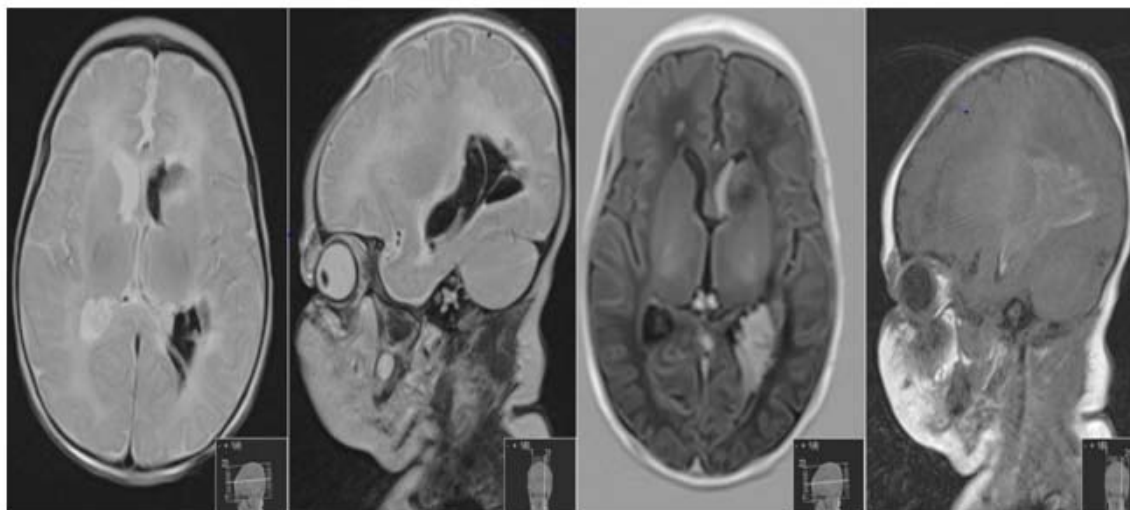
#### Conflict of Interest

None.

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*Fig. 1: MRI, Sagittal view showing Intraventricular Hemorrhage*



*Fig. 2: US showing Pleural Effusion*



*Fig. 3: US showing Ascites*

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# Incarceration of Gravid Uterus as a Content of Anterior Abdominal Wall Hernia Secondary to Diverification of Recti

By Dr. Bharati Sahu, Dr. Archana Thakur, Dr. Nazreen, Dr. Nupur  
& Dr. Monika

**Introduction:** The herniation of a gravid uterus through a diverification of recti is a very rare occurrence. It may lead to some serious complications, such as incarceration and subsequent strangulation of the gravid uterus. Here we report a case of herniation of gravid uterus as a content of the anterior abdominal wall hernia secondary to diverification of recti, in a woman with previously normal delivered child.

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# Incarceration of Gravid Uterus as a Content of Anterior Abdominal Wall Hernia Secondary to Diverification of Recti

Dr. Bharati Sahu <sup>α</sup>, Dr. Archana Thakur <sup>σ</sup>, Dr. Nazreen <sup>ρ</sup>, Dr. Nupur <sup>ω</sup> & Dr. Monika <sup>¥</sup>

## I. INTRODUCTION

The herniation of a gravid uterus through a diverification of recti is a very rare occurrence. It may lead to some serious complications, such as incarceration and subsequent strangulation of the gravid uterus. Here we report a case of herniation of gravid uterus as a content of the anterior abdominal wall hernia secondary to diverification of recti, in a woman with previously normal delivered child.

## II. CASE REPORT

A 25-year-old woman presented with G2P1L1A0 with 36 weeks + 3 days gestation with abdominal wall hernia with incarceration of gravid uterus with abdominal pain. Her obstetric history revealed previous vaginally

delivered male child of 3 years age. On examination, the patient was of average built, with pallor and stable vitals. Abdominal examination revealed, thin peppery skin, visible dilated veins and a 34 weeks size gravid uterus with part of uterus visible through 5x5cm defect of abdominal wall with signs of vascular compromise present over skin. FHS was localized and tenderness was present during examination. On per vaginal examination cervical os was admitting two finger, early effaced, membrane present, adequate pelvis and vertex high up. Ultrasound showed a single live fetus of 35 weeks + 3 days of gestation with breech presentation with placenta of grade 2 maturity, baby weight of 2.6 kg, with anterior wall hernia with normal Doppler and no signs of congenital anomalies.



Herniation of the gravid uterus as a content of hernial wall is rare possibly due to the fact, it is usually too large to enter the hernial sac. Till now only 18 cases of anterior abdominal wall hernia complicated by gravid uterus have been reported. With approximately 13 were incisional hernia and 5 were umbilical hernia.<sup>1</sup> In this rare condition reported complications are IUGR, APH, strangulation, intrauterine death, rupture of lower uterine segment and burst abdomen.<sup>2</sup>

The patient was admitted to hospital and kept under observation. Antibacterial skin ointment was applied over the affected skin and dressing done. Simultaneously, patient was given i/v antibiotics, to colytics and steroid to prevent premature delivery and early fetal lung maturity. Maternal and fetal prognosis explained to attenders. Continues fetal monitoring was done for any signs of strangulation-like abdominal pain and vomiting. Daily fetal movement count done. An elective caesarean section was planned at 37 weeks of gestation as patient complained of abdominal pain. A male baby weighing 2.5kg with Apgar scores of 5/10 at

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1 min and 6/10 at 5 min, was delivered. Herniorrhaphy was done without a mesh. Postoperatively, the patient was given injectable antibiotics and other supportive treatment for 10 days as patient was having cough and an abdominal binder was also provided. Alternate sutures were removed on the 10<sup>th</sup> postoperative day and complete sutures on 12<sup>th</sup> postoperative day. The patient was discharged with stable vitals. Patient came for follow up after 1 week with healthy baby and healthy wound.

### III. DISCUSSION

It has been observed that the incidence of abdominal wall hernia, with gravid uterus as a content of anterior abdominal wall hernia secondary to diverification of recti, is very rare (approximately <1%)<sup>3</sup>. The possible risk factor for the development of incarceration of uterus with diverification of recti is nutritional deficiency. Hernial defect repair was not possible during antenatal period due to enlarged gravid uterus<sup>4</sup>. Conservative management during the antenatal period, followed by herniorrhaphy as primary closure seems to be the treatment of choice in such cases<sup>5</sup>. Cesarean section is the treatment of choice for successful outcome in case of herniated gravid uterus.<sup>6</sup>

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# Emergency Contraception: What the General Practitioners Think ?

By Raymond Surya, Budi Iman Santoso & Surahman Hakim

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**Keywords:** birth control, pregnancy, emergency contraception.

**GJMR-E Classification:** NLMC Code: WP 630



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# Emergency Contraception: What the General Practitioners Think ?

Raymond Surya <sup>α</sup>, Budi Iman Santoso <sup>σ</sup> & Surahman Hakim <sup>ρ</sup>

**Abstract- Objective:** Determine the knowledge, attitude and practice (KAP) among general practitioners in Indonesia about emergency contraception (EC).

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**Results:** We obtained a total of 195 respondents who completed answering all questions. Most of the respondents (61.5%) had a lack of knowledge about EC. The attitude score of 50.3% among the respondents was below the mean score (negative attitude). A total of 188 respondents had heard about EC, and only 14 had ever prescribed EC pills. The most common reason for not prescribing EC was because of no indication on administration (72.8%).

**Conclusion:** Comprehensive educational intervention and training for all fresh graduate general practitioners must be conducted to improve the quality of service on contraception.

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## 1. INTRODUCTION

At least 210 million pregnancies occur worldwide every year, among which about 80 million (38%) include unplanned pregnancies and about 46 million (22%) end in abortion.<sup>(1)</sup> Iwu DU and Ariane U stated that about 2.5 million abortions occur in Indonesia annually and 20%-60% of them were induced. This implies a ratio of 43 abortions to 100 live births or 30% of pregnancies. Women undergoing an abortion were found to be aged 20 years or older (92%), and the incidence of abortion was higher in the rural area (60%) than in the city (30%).<sup>(2)</sup> In reality, based on the Indonesian abortion law stated in 1992, an abortion is generally accepted only if the woman provides a confirmation from a doctor that her pregnancy is life-threatening, a consent letter from her husband or a family member, a positive pregnancy test result and a statement that she would practice contraception afterwards. In Indonesia, several women often seek unsafe abortion procedures performed by untrained providers, which, in turn, lead to complications and

maternal deaths. Although data regarding abortion-associated mortality in Indonesia are unavailable, the World Health Organization (WHO) estimates that unsafe abortion contributes to 14% of maternal deaths in Southeast Asian countries that have highly restricted abortion laws.<sup>(3)</sup>

Emergency contraception (EC) is a back-up method applied after the failure of using contraception or unprotected intercourse to prevent an unwanted pregnancy. The procedure for EC consists of hormonal and mechanical methods. A hormonal EC pill, sometimes referred to as a 'morning-after' or a 'postcoital' pill, contains higher levels of a hormone in daily oral hormonal contraceptives. In Indonesia, the EC pill is known as Pil KB Andalan Postpil or Valenor 2or Postinor 2 containing 0.75 mg of levonorgestrel (LNG) each. It should be taken as two doses and is 75%-95% effective when taken within 72 h of unprotected intercourse.<sup>(4)</sup> The most popular mechanism of action of the EC pill is the prevention of ovulation. An intrauterine device (IUD) is another EC method that has been shown to be effective for up to 12 days after unprotected sexual intercourse. The mechanism of action of an IUD is the stimulation of inflammatory response of the endometrial lining and the inhibition of implantation of the zygote.<sup>(5)</sup>

The use of EC has been interfered by a lack of adequate information on its mechanism of action, benefits and fears associated with misconception. In addition, the judgemental attitude of providers towards the clients who ask for EC hampers the use of EC. In some countries, the clients need medical prescription to obtain the EC pills, which can delay the optimal time for consuming.<sup>(6)</sup> In Indonesia, the EC pill is supplied over the counter by a pharmacist; therefore, the clients can easily buy one. The easiness in obtaining the EC pill must be supported by physician knowledge to provide the correct information about its use. Lack of appropriate knowledge can lead to wrong advice and prescription, which can trigger sexual liberty and the associated complications. The knowledge, attitude and practice (KAP) of physicians regarding EC have been extensively investigated in the Western countries; however, there is limited information in Indonesia in this regard. Therefore, this study was conducted to determine the KAP among general practitioners in Indonesia about EC.

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## II. METHODS

### a) Study Design

A cross-sectional descriptive study was conducted on internship doctors in Indonesia from July to August 2016. We recruited the participants through simple random sampling by distributing an online questionnaire. Subjects who would like to participate in the study could fill the online questionnaire directly by reading the aim of the study and the instructions. The questionnaire included eight characteristic demographic questions. In addition, to determine the KAP of physicians about EC, we asked 15 questions consisting of 5 knowledge, 8 attitude and 2 practice questions. We adopted the questionnaire based on several previously published studies.<sup>(6-9)</sup> We developed the questions as appropriate to the culture and then translated it into the Indonesian language.

### b) Score Determination for KAP

The respondents were asked about their KAP towards EC. The knowledge was assessed using a series of questions on the identification of EC indication, on the time frame for effective use, side effects and appropriate candidates for use. The providers' knowledge was considered as 'good' if they correctly answered 10 or more of the 13 knowledge questions. Scores of 6-9 were considered as 'fair' and less than 6 as 'poor'.

The respondents' attitudes towards prescribing EC were determined through several questions, including their perception about EC, the desire to prescribe EC, and the opinion about EC education during medical school. The Likert scale was used to determine this attitude, which was represented as strongly disagree, disagree, agree and strongly agree. If the providers' score was 15 or less, we considered it as a 'negative' attitude, while a score more than 16 was considered as a 'positive' attitude. In addition, we asked the respondents two questions about their practice on EC, including ever prescribing the EC and the reason for refusing to prescribe EC.

### c) Inclusion Criteria

The inclusion criterion was all general practitioners who were doing the internship in Indonesia during the study period, so that that they would have a similar ability in the contraception service. Internship is the period after the completion of medical school in Indonesia. It takes a year to dedicate as a general practitioner under supervision in the primary health care and the hospital. The exclusion criterion was general practitioners who postponed the internship due to any reason. We considered that the respondents who had completed the online questionnaire had given their implied consent to this study.

### d) Variables

The independent variables in this study were medical school and internship region. The dependent

variable included the total knowledge score, which was the summation of true statements about EC, indication for prescribing EC, and the best interval time to prescribe the EC pill. We summed up the attitude statements of increasing free sex and reducing other methods of contraception caused by EC, refusing to prescribe EC due to religion or belief objection, familiarising EC widely, prescribing EC to clients as an indication and feeling as obtained adequate information about EC during medical school.

### e) Validity and Reliability Test

To obtain consistent results, the questionnaire must fulfil the validity and reliability tests. The first 30 respondents were considered as the samples in our study. In the validity test, we obtained 2 of 5 knowledge questions and 2 of 8 attitude questions that were not valid, whereas the correlation coefficient (r) arithmetic was less than (r) table. We considered that those questions were essential to describe the distribution; thus, we displayed only on table not for analysing. After performing the validity test, we continued to the reliability test. The Cronbach alpha was found to be 0.56 for all valid questions. However, it was less than 0.6, and we determined that the respondents could understand all questions clearly.

### f) Sample Size and Data Analysis

To estimate the sample size, we used the nominal sample size for estimation of proportion with  $Z_{\alpha}$  1.96, estimation in population of 50%, and absolute precision of 0.10. Of this formula, we obtained that the minimal sample size was 97 subjects. However, due to descriptive study, we recruited all participants finishing the online questionnaire. Descriptive statistics were used for data analysis using SPSS for Windows version 23.0 for Windows. Normality was assessed using the Kolmogorov - Smirnov test for all demographic characteristic data. Descriptive data are presented in terms of frequency, percentage, median and minimum -maximum. We categorised the medical school of general practitioners based on two aspects, namely, those coming from the government medical school and those coming from the public medical school. The internship region was categorised as 1 for Sumatra, 2 for Java, 3 for Borneo, 4 for Sulawesi, 5 for Papua and 6 for Bali and Nusa Tenggara. Validity test using Pearson correlation and reliability test using Cronbach's alpha were carried out for questions describing the KAP of EC in the questionnaire.

### g) Informed Consent

Before the beginning of this study, we informed about an online informed consent to the participants. We considered that the respondents agreed to participate in this study if they had answered all the questions.

### III. RESULTS

To maximise the study participation and data collection, we sent requests to fill out the online questionnaire through each internship region by sending a message. During the 2 months of circulating the online questionnaire, we obtained 195 respondents who completed answering all the questions. According to our prediction, there were about 3,000 general practitioners doing internship in a year (the questionnaire is provided as a supplement).

Overall, the majority of respondents (61.5%) had a lack of knowledge about EC (table 2), as 20.0% of them obtained the scores of 3-5 and 41.5% of them obtained the scores 6-9. Only 38.5% of them had good knowledge (scores of 10-13). The maximum score was 13. Regarding the attitude, the mean score was 15.7 (SD 2.3) (table 3). The attitude score of 50.3% of respondents was below the mean value (negative attitude), whereas the remaining (49.7%) obtained a score above the mean value (positive attitude). The minimum attitude score was 6, and the maximum was 24. Meanwhile, the practice of respondents was shown at table 4.

### IV. DISCUSSION

Our study revealed that almost all general practitioners (96.4%) who did the internship had heard about EC. This result was similar to that reported from Iran<sup>(4)</sup>, Nigeria<sup>(6-8)</sup>, the Caribbean<sup>(9)</sup> and Indonesia<sup>(10)</sup>. The respondents mentioned that the commonest indication for EC was following a rape and a condom breakage. This result was similar to that reported by IO MB, et al.<sup>(6)</sup>, who showed that 95.6% of respondents were aware that sexual assault was one of the indications for EC. Meanwhile, Oriki and Omietimi<sup>(9)</sup> reported that only 76% of interviewed doctors stated about rape for the indication of EC. A plausible explanation for the difference is that our respondents were just graduated from medical school, so that they would still have a better memory of their undergraduate knowledge.

There is a common misconception that EC is an abortifacient because only 64.1% of respondents answered correctly. This prevalence was better than that reported by the study of Hamza MA, et al. in Pakistan<sup>(11)</sup>, where only 33% of subjects answered that EC was not an abortifacient method and 42% were unsure.

In general, there was poor knowledge regarding the procedure and the optimal time to use EC pills after unprotected sexual intercourse. Only 33.3% of our respondents stated that EC was safe and effective, followed by 23.1% who answered correctly for the best time interval for taking EC pills. For safety reasons, the WHO guidelines on EC services explain that repeated use of EC does not increase the risk of health and that EC is not a reason for denying women access to

treatment.<sup>(12)</sup> In fact, LNG 1.5 mg (single dose) is as effective as post coital contraceptives for up to 5 days with the best time interval within 72 h of intercourse (relative risk (RR) 0.51; 95% CI 0.31-0.84). Meanwhile, a copper IUD shows a high efficacy as EC; however, it is an invasive procedure and requires trained providers and sterilised facilities to insert, and hence, it is often not the first choice for clients.<sup>(5)</sup> Therefore, it can be said that EC is safe and effective.

Around 52.4% of respondents disagreed that they obtained sufficient knowledge about EC during medical school. This might be due to the lack of quality teaching methods or adequate attention towards the topic of reproductive health in the undergraduate medical education curriculum. In fact, the respondents were fresh graduates, so that we expected that they had high knowledge about EC.

Polis CB, et al.<sup>(13)</sup> Pointed out that administering an EC pill to women could guarantee that they possessed it in case they needed it. More than 50% of our respondents stated that EC was important in the daily practice, should be spread widely to the population and would not decrease the use of regular contraceptive methods. Melanie AG, et al.<sup>(14)</sup> and Terri LW, et al.<sup>(15)</sup> Concluded that making EC pills widely available would not increase risk-taking behaviour or adversely affect regular contraceptive use.

Although the majority of respondents in our study had heard about EC, only 7.2% of internship doctors had ever prescribed the EC pills. This percentage was lower than that of previous studies, such as in Nigeria, Pakistan and USA. In our study, the third most common reason for refusing to prescribe EC was that the clients were not on indication (72.8%), the method was not available (34.4%) and they did not have sufficient information about the method (23.6%). Data about violence against women surveyed in Indonesia showed that 11.3% of women have undergone harassment, which could be due to husband, parents, family, neighbour, boss, co-workers and others.<sup>(16)</sup> Meanwhile, the UNDP report in 2016 described that among all Papua women aged 14-64 years, 38% of them reported having experienced any physical violence from a non-partner in their lifetime.<sup>(17)</sup> The high prevalence of harassment or sexual abuse is not followed by the high prevalence of EC prescription experience from the respondents. This is because of several reasons. In Indonesia, sex is a 'taboo', so that when a woman experiences sexual abuse, she is embarrassed to ask for help to a health professional; furthermore, she does not tell anyone that she has experienced it until she gets pregnant. In addition, the victim does not reveal about the EC method to prevent an unwanted pregnancy because of less socialisation about it. When she comes to a health professional, she is not on indication anymore; therefore, the respondents



in our study stated that the most common reason was that the clients were not on indication.

We consider that the respondents have poor knowledge about EC. Although most of them knew about the indication on EC, 34.4% of them said that the method was not available. In fact, we can provide EC from the available hormonal oral contraceptives at the primary health care. We only increase the dose of LNG up to the minimum dose requirement for EC (1.5 mg). Apart from that, we can offer the copper IUD as an alternative EC method, which is available at all the primary health care centres in Indonesia.

The limitation of our study is the small sample size of internship doctors in Indonesia. Moreover, the data are based on self-report, which can result in subject recall bias. Meanwhile, we recruited respondents with a similar condition, i.e. only internship doctors. Internship doctors are the general practitioners who have just graduated, on average 6 months to 1 year before, so that we can determine the quality of reproductive health education in their medical school. They have fresh memory of the knowledge and similar experiences in health services.

Therefore, effective educational interventions are likely to improve the general practitioners' knowledge, and reproductive health training can be the key to escalate the ability of providing the method. In addition, the health department in cooperation with Badan Koordinasi Keluarga Berencana Nasional (BKKBN) should socialise to the public about the indication and the access procedure to obtain EC. The highest affectivity of EC should be at proper time intervals. EC has the potential to prevent unwanted pregnancies among adolescents or young adults who comprise the majority of sexually active population. Consequently, we can minimise unsafe abortions, which have an effect on the maternal mortality rate.

## V. CONCLUSION

Most of the respondents were familiar with EC; however, they do not have sufficient knowledge about EC as expected from a physician. We recommend conducting a comprehensive educational intervention and also reproductive health training for all fresh graduate general practitioners before doing the internship to improve the quality of service on contraception and to prevent unwanted pregnancies and unsafe abortions.

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### Conflict of Interest Statement

The authors declare no conflict of interest.

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**Table 1:** Characteristics of Respondents Who Participated in This Study (N=195)

Characteristics	N (%)
<i>Age (Years)</i>	
Median (Min-Max)	25 (21-38)
<i>Religion</i>	
Muslim	100 (51.3)
Catholics	39 (20.0)
Christian	40 (20.5)
Hindu	8 (4.1)
Buddhist	8 (4.1)
<i>Marital Status</i>	
Single	164 (84.1)
Married	30 (15.4)
Divorce	1 (0.5)
<i>Educational Level</i>	
Bachelor Degree / Medical Doctor	190 (97.4)
Master Degree	5 (2.6)
<i>Medical School</i>	
Government	116 (59.5)
Public	79 (40.5)
<i>Graduation Year</i>	
2013	5 (2.6)
2014	10 (5.1)
2015	169 (86.7)
2016	10 (5.1)
N/A	1 (0.5)
<i>Internship Region</i>	
Sumatra	16 (8.2)
Java	108 (55.4)
Bali and Nusa Tenggara	27 (13.9)
Borneo	9 (4.6)
Sulawesi	23 (11.8)
Papua	12 (6.2)

**Table 2:** Percentage of Internship Doctors Who Answered Knowledge Questions Correctly (N=195)

Statements	N (%)
I have heard about EC	188 (96.4)
<i>Source of information on EC</i>	
Formal education	186 (95.4)
Congress	54 (27.7)
Print/electronic media	61 (31.3)
Working place	68 (34.9)
Others	22 (11.3)
<i>The following statements are true about EC:</i>	
Used for unprotected intercourse	180 (92.3)
Used for inconsistent contraceptive users	114 (58.5)
Not routinely used	147 (75.4)
Safe and effective	65 (33.3)
Not for abortive method	125 (64.1)
Not for protecting from sexually transmitted disease (STD)	191 (97.9)
<i>Indication for using EC:</i>	
Rape	170 (87.2)
Unprotected intercourse	138 (70.8)
Condom breakage	151 (77.4)
Detached intrauterine device (IUD)	110 (56.4)
Missed pills	116 (59.5)
Missed injection	87 (44.6)
Pregnancy test should be conducted before prescribing the EC methods-False*	65 (33.3)
The commonest side effect of EC pill is nausea and vomiting-True*	118 (60.5)
The best time interval to use EC pill is less than 72 h-True	45 (23.1)

\* The question is not valid

**Table 3:** Attitudes about Emergency Contraception (EC) (N=195)

Statements	Strongly Disagree N (%)	Disagree N (%)	Agree N (%)	Strongly Agree N (%)
EC are important for daily practice*	32 (16.4)	75 (38.5)	66 (33.8)	22 (11.3)
EC will increase free sex	23 (11.8)	42 (21.5)	65 (33.3)	65 (33.3)
EC will reduce other methods of contraceptive user	43 (22.1)	86 (44.1)	54 (27.7)	12 (6.2)
I will refer to OB-GYN to prescribe the EC methods*	15 (7.7)	80 (41.0)	71 (36.4)	29 (14.9)
I am not pleasant to prescribe the EC due to my religion / belief	29 (14.9)	93 (47.7)	47 (24.1)	26 (13.3)
EC should be familiarised widely among population	35 (17.9)	48 (24.6)	71 (36.4)	41 (21.0)
I will prescribe EC to the clients as an indication	1 (0.5)	27 (13.8)	92 (47.2)	75 (38.5)
I felt obtaining enough material about EC in medical school	12 (6.2)	90 (46.2)	83 (42.6)	10 (5.1)

\* The question is not valid

**Table 4:** Practice about Emergency Contraception (EC) (N=195)

Statements	N (%)
I Have Ever Prescribed the EC Pill	14 (7.2)
<i>I Refuse to Prescribe the EC because / due to</i>	
Clients have Contraindication	102 (5.3)
Clients are not on Indication	142 (72.8)
Did not know Enough about Method	46 (23.6)
Method was not Available	67 (34.4)
Religion / Belief Objection	41 (21.0)
Side Effects	10 (5.1)
Other Reasons	13 (6.7)



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# Tranexamic Acid Coated or Eluted Uterine Balloon and Co-Attached Cervical Shutter in Post Partum Haemorrhage. A New Combatant in the Armamentarium, Not Merely a Balloon but More

By Abd El Aal Nasser Kamal

**Abstract-** Described herein a Tranexamic Acid (TXA) - Coated or Eluted Uterine Balloon for use in an intra uterine location for primary management of postpartum haemorrhage (PPH). It enforces the tamponade effect of currently used non medicated uterine balloons with an additional inbuilt mechanism of local steady release of the antibrinolytic TXA into uterine cavity that has been evidenced to contribute to haemostasis in cases of PPH. The invention ushers a new era of utilizing the uterine balloon surface coat as a delivery vehicle for TXA. This can be achieved via different techniques including and not limited to matrix coating or eluting of nanoparticulate TXA in the outermost layer of the balloon .TXA coated or eluted balloon replenish non medicated balloons with a therapeutic modality of the TXA related - antifibrinolysis especially in hemorrhages known to be associated with coagulopathy.

*GJMR-E Classification: NLMC Code: WP 440*



*Strictly as per the compliance and regulations of:*



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## I. FIELD OF THE INVENTION

This invention relates to a functional development of currently used uterine balloons in cases of PPH, in the field of Obstetrics and modifying them to be a delivery vehicle for drugs known of their haemostatic action onto the bleeding site, i.e. uterine cavity. TXA coated or eluted uterine balloon will avail the non medicated uterine balloons in use nowadays for management of PPH with a dual integrated pharmacomechanical mechanism, along with an innovative

mechanism, that is, the cervical shutter which safeguards against external fast escape of the medication from the uterine cavity, thus allowing drug retention inside the uterine cavity for a reasonable time so as to achieve its therapeutic effect. Utilization of outer coat of balloon as a polymer-based vehicle used for delivering tranexamic acid and other haemostatic agents can be brought about by the use of a drug coating or eluting matrices technology and a variety of different water soluble and lipid soluble specialized polymers. The latter will be selected according to which suits better the most efficient steady state of intra cavity drug release.

## II. BACKGROUND OF THE INVENTION

The object of this invention is to enforce a dual pharmacomechanical effect of TXA medicated intrauterine balloon in the armamentarium of managing postpartum hemorrhage (PPH).

[0001]- Since PPH is one of the leading causes of maternal mortality worldwide, various strategies have been developed to prevent and control it. World Health Organization, the International Federation of Gynecology and Obstetrics, and the Royal College of Obstetricians and Gynaecologists all recommend a uterine balloon tamponade (UBT) if uterotonics and uterine massage fail to control bleeding. Intrauterine balloon tamponade has been suggested as an effective, easily administered minimally invasive treatment option to control uterine bleeding while and fertility sparing procedure<sup>[1,2,3]</sup>.

[0002]- Multiple types of balloons are available, including Bakri balloon, BT-cath balloon tamponade catheter, Foley catheters, Rusch balloon, condom catheters and the Sengstaken-Blakemore tube. The Bakri postpartum balloon<sup>[4]</sup> and the BT - balloon tamponade catheter are specifically designed for postpartum intrauterine tamponade, and they are the only such devices approved by the US Food and Drug Administration for this application<sup>[5]</sup>.

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[0003]- It is believed that pressure greater than systemic arterial pressure applied to the uterine wall by the inflated balloon is the mechanism of controlling the hemorrhage. This pressure can be achieved by inflating different balloons by different volumes<sup>[6]</sup>.

[0004]- It has been also reported that TXA decreases postpartum blood loss after vaginal birth and after caesarean section<sup>[7][8]</sup>. A systematic review and meta-analysis indicate strong evidence that intravenous administration of tranexamic acid (TXA) reduces blood transfusion in surgery<sup>[9]</sup>.

[0005]- Although most of the randomized studies or the cohort studies have suggested no statistically significant increase of thrombo embolism with use of TXA, sporadic cases of pulmonary embolism have been reported<sup>[10]</sup>.

[0006]- The true risk of thromboembolism by TXA remains uncertain because those studies have not statistical powers enough to detect the risks of rare events as pulmonary embolism. However, It stays hitherto as theoretical risk.

[0007]- Recently, haemostatic effects of topical or intracavitary administration of TXA have been also shown in cardiothoracic or orthopedic surgery. Recent meta-analyses of several randomized controlled trials have shown that tranexamic acid reduces peri - and postoperative blood loss, blood transfusion requirements and reoperations caused by bleedings.<sup>[11][12]</sup>

<sup>13</sup><https://www.hindawi.com/journals/crig/2015/195036/-B14>].

[0008]- Topical use may pose a reduced risk, if any, of thromboembolism because the serum concentration of TXA in topical use would be much lower than systemic use.

[0009]- Unlike in other fields of surgery, there has been no data on the topical or intra cavitary use of TXA in obstetrics, possibly due to technical difficulties in hollow organs with an opening like a uterus. In one study TXA has been added to a piece of gauze wrapped around a ballon and it has been found in such way it was possible to deliver a high concentration of the TXA at bleeding spots inside the uterus ant to add effectively to cessation of PPH<sup>[14]</sup>.

[0010]- Moreover, TXA competitively inhibits activation of plasminogen, thereby reducing conversion of plasminogen to plasmin (fibrinolysin), an enzyme that degrades fibrin clots, fibrinogen, and other plasma proteins, including the procoagulant factors V and VIII. Tranexamic acid also directly inhibits plasmin activity, but higher doses are required than are needed to reduce plasmin formation<sup>[15]</sup>.

[0011]- In recent years the extensive trial comprising more than 20,000 patients in severe trauma with massive bleedings using tranexamic acid was presented i.e. CRASH-2 (Clinical Randomization of an

Antifibrinolytic in Significant Haemorrhage). It showed that the survival was increased when tranexamic acid was given early after the accident compared to placebo<sup>[16]</sup>.

[0012]- Of utmost importance is the WOMAN (World Maternal Antifibrinolytic), a randomized, double-blind, placebo controlled trial among 15,000 with clinical diagnosis of postpartum haemorrhage that pointed out the efficacy of Tranexamic acid in reducing maternal mortality from post-partum haemorrhage with no adverse effects. The previous study has stressed upon that when used as a treatment for postpartum haemorrhage, tranexamic acid should be given as soon as possible after bleeding onset<sup>[17]</sup>.

[0013]- Over the past decade, a novel opportunity has been widely used in endovascular coronary ischaemic management, namely the surface coatings in surface mediated-drug delivery. In these applications, deposited polymer film act as both a coating to modulate surface properties and a reservoir for active therapeutic cargo and delivery vehicle (i.e. endovascular angioplasty with anti proliferative paclitaxel coated or eluted balloon catheter as to prevent re stenosis).

[0014]- The fore mentioned data led to the ideation of this invention with such conception of making use of the evidence based of safety and efficacy of local delivery of TXA in comparison to systemic route, maximizing the efficacy and functionality of currently used non medicated uterine balloons in postpartum haemorrhage through inbuilt medication with TXA utilizing the currently used surface coating or eluting techniques and slow release of nanoparticles of such drug from polymeric coat.

[0015]- This ideation represents a meeting point of evidence based research at the interface of chemistry, nanotechnology, clinical pharmacology and bio medicine to develop a safe and efficacious aid in managing PPH. It allows utilization of a dual pharmacomechanical effects to enforce the efficiency of the currently used non medicated uterine balloon via TXA topical intrauterine release from drug nano particles coated matrix in the balloon surface which is more safe than systemic administration as regards thromboembolic risk. Together with an innovative adaptive back up mechanism to retain the released drug in utero without being flushed out rapidly via the co attached cervical shutter or "Barricade", this generation of uterine medicated balloons would be an effective measure in the armamentarium of the treatment of PPH.

### III. DESCRIPTION OF THE INVENTION

The present invention provides a basically and specifically medicated uterine balloon that comprises the dual grasp of both the mechanical compression of the classical uterine balloon, and a unique inbuilt design



that can enable topical intrauterine release of TXA through its outer surface. So, it ushers a new era of currently used coated or eluted balloon with a different location (intrauterine), different indication (PPH) and a different medication (TXA, and other haemostatics).

Basically, the currently used balloons particularly B-T catheter balloon, a pear-shaped balloon tamponade catheter for controlling uterine postpartum hemorrhage. (Utah Medical products Inc. –patent US 8123773 B1) are blank or non medicated, so they offer solely a mechanical tamponade effect.

However, 2 achievements in the current invention that constitutes an additional dimension to these currently used balloons:-

*A-Basically*, and specifically to this invention is first mention of utility of tranexamic acid (TXA)- coated or eluted uterine balloon in cases of PPH. The outer coat is functionally modified to act as a "cargo" or a delivery vehicle for TXA and possibly other haemostatics which will add a therapeutic dimension to the currently used plain uterine balloons especially in those cases of PPH co-associated with a coagulopathic defect. Examples for this drug delivery routes are many in the literature and some embodiments will be mentioned later.

*B-Cervical shutter, "Barricade"*: A back up mechanism to allow intra uterine residency of the released TXA. It is a cone shaped screw plug moving along the screw bar of the mid vaginal portion of the balloon catheter, the outer surface of which is modified as a screw bar allowing the Barricade to move towards the cervix shutting it at the cervico vaginal junction to halt the fast downward egress of the released drug, an additional mechanism for its longer topic residency inside the uterine cavity. Additional advantage of barricade screw are fixative and immobilizing influence on the balloon causing its strict apposition with endometrial surface and providing an extra counter pressure on the lower uterine segment which may be the site of bleeding in abnormally adherent placenta.

[0016]- In one embodiment, Thin film polymers can be used as a drug cargo in the TXA medicated uterine balloon by either surface coating and drug capturing via surface folding or eluting techniques may be methacrylic acid copolymers. The balloons which are coated while the balloon is inflated are preferred as it enables a coating procedure while the balloon is inflated and the sufficient drug adherence in the dry state allows for a subsequent folding without significant drug loss.

[0017]- In another embodiment, the polymers can be hydroxypropyl cellulose phthalate, hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate, polyvinylacetate phthalate, polyvinylpyrrolidone phthalate, and the like. Coating morphology, coating thickness, drug-loss, drug-transfer to the uterine cavity, residual drug-concentration on the balloon surface and entire drug-load should be studied to choose most

appropriate drug delivery mode with known biodegradability and biocompatibility.

[0018]- In one embodiment, a coating technology to deliver the TXA without the use of a permanent polymer carrier can be utilized. The ideal coating formulation should maximize the total dose that can deliver TXA onto the balloon surface at an efficient concentration may vary according to factors involved in the successful design of balloon-based delivery systems, including drug release kinetics, matrix coating transfer, trans cavitary drug partitioning, dissolution rate and release of unbound active drug. It is noteworthy, this system of TXA coated or eluted uterine balloon with close apposition of the balloon to uterine cavity because of immobilizing action and cervical shutter mechanism guarantees an efficient release of drug at a satisfactory concentration and for a duration lasting up to 24 hours.

[0019]- In another embodiment, Liposomes can be utilized as nanocarriers for targeted TXA delivery. They are defined as phospholipid vesicles consisting of one or more concentric lipid bilayers enclosing discrete aqueous spaces. The unique ability of liposomal systems to entrap both lipophilic and hydrophilic compounds enables a diverse range of drugs to be encapsulated by these vesicles. Liposomes present as an attractive delivery system due to their flexible physicochemical and biophysical properties, which allow easy manipulation to address different delivery considerations.

[0020]- In another embodiment a TXA coated balloon may be preferentially opted when put head to head with TXA eluted one as the potential advantages of drug coating technology compared to eluting process are homogenous drug transfer, rapid drug release, and absence of remaining polymer implants which may be an appropriate option in case of PPH<sup>[18]</sup>.

[0021]- In one embodiment, Smart polymers can be the delivery vehicle. In particular, smart polymeric drug delivery systems have been explored as "intelligent" delivery systems able to release, at the appropriate time and site of action, entrapped drugs in response to specific physiological triggers. These polymers exhibit a non-linear response to a small stimulus leading to a macroscopic alteration in their structure/properties. The responses vary widely from swelling/contraction to disintegration. The most fascinating features of the smart polymers arise from their versatility and tunable sensitivity<sup>[19]</sup>.

[0022]- As wherein treating severe hemorrhage by external measures in open hollow organs like uterus is challenging because blood flow pushes hemostatic agents outward, reducing their efficacy. Accordingly, in one embodiment the self-propelling particles with its capability of autonomus movement with upstream orientation may be used for delivering therapeutics, such as coagulation factors deep into targeted location during hemorrhage in an upstream blood flow direction<sup>[20]</sup>.



[0023]- In any of the fore-mentioned embodiments, in this invention there is a modified balloon catheter shaft, where the external surface of balloon catheter at its intra vaginal portion presents a spiraled inclined plane on its external surface for a considerable length to cover a reasonable distance that allow screwing of the cervical shutter "Barricade". Such distance of the screw bar of the balloon catheter from mid vagina to the cervix measures 50mm and additional extra length of the screw bar from cervix to the lower uterine segment LUS that compensates for variations in lengths of uterine cavity (approximately 20mm-30mm) so as to allow an available screw bar for movement of screw plug distally to the required distance when the catheter is pulled downwards to stop short at cervico vaginal junction to offer a cervical shut effect. The latter allows a reasonable intrauterine residence of the medication. Noteworthy, the screw bar portion of the balloon catheter should be made harder in consistency than the remaining working length but still have a degree of flexibility. The target behind making this screw from a relatively harder polyurethane polymer is to allow some durability in the face of the moving screw plug.

[0024]- In the fore-mentioned embodiment, the co attached cervical shutter or "Barricade" is a cone shaped screw vaginal plug with its narrow proximal and distal wider portions is designated to work on the screw portion of balloon catheter. The screw plug weighs approximately 200-300 grams, measuring 40mm in length, 30mm in the distal widest diameter and tapering proximally through its length with the narrowest proximal outer diameter measuring 20mm Fig. (2). The "Barricade" screw plug should be made of material that guarantee resilience, inertness and non toxicity .It should have a smoothly surfaced outline to be easily manipulated (screwed) onto the screw bar of the external surface of the balloon and locked at the cervico-vaginal junction to serve as a cervical shutter.

[0025]- In reference to embodiments of [0023] & [0024], such modification does not only offer a cervical shutter but also provides the balloon with a self retaining capability without a need for attachment to the patient legging or attachment to an external weight which is the case in currently used balloons (Bakri B.T.). Moreover such embodiment enforces the balloon with extra counter compression especially on the adjacent lower uterine segment which in some cases may be the source of bleeding as in abnormally implanted and adherent placenta.

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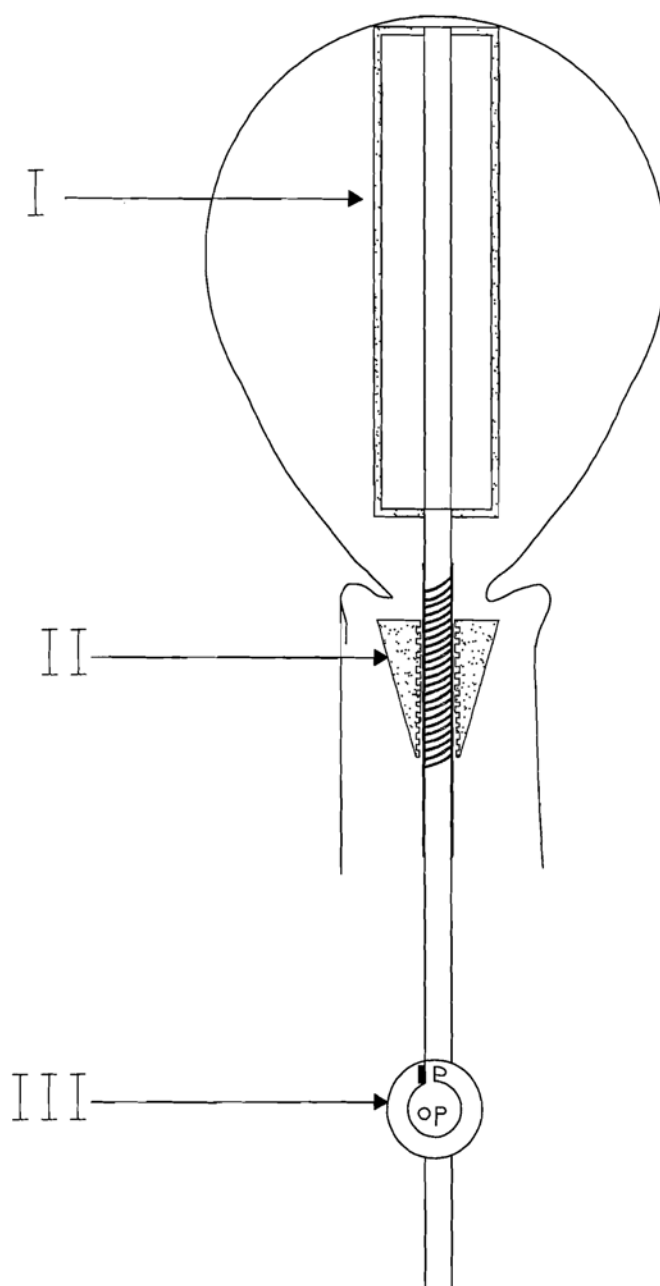
Cited Patent	Filing Date	Publication Date Applicant	Title
US 8123773 B1	Sep. 10, 2008	Feb. 28, 2012 Utah Medical Products Inc	PPH Tamponade Balloon Catheter

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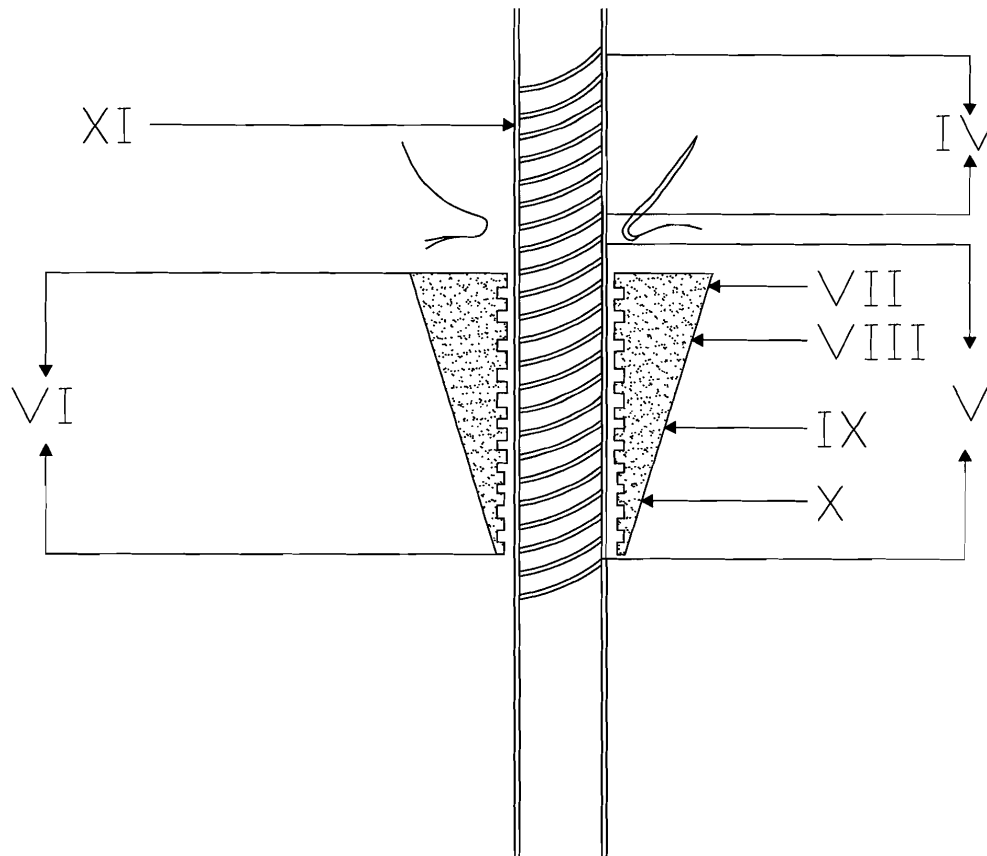


**Fig. 1:** Schematic Diagram of the TXA Uterine Coated or Eluted Balloon in Situ in a Deflated State Highlighting its 2 Unique Attributes (I & II):

I - TXA - Medicated (Coated or Eluted) Balloon Surface.

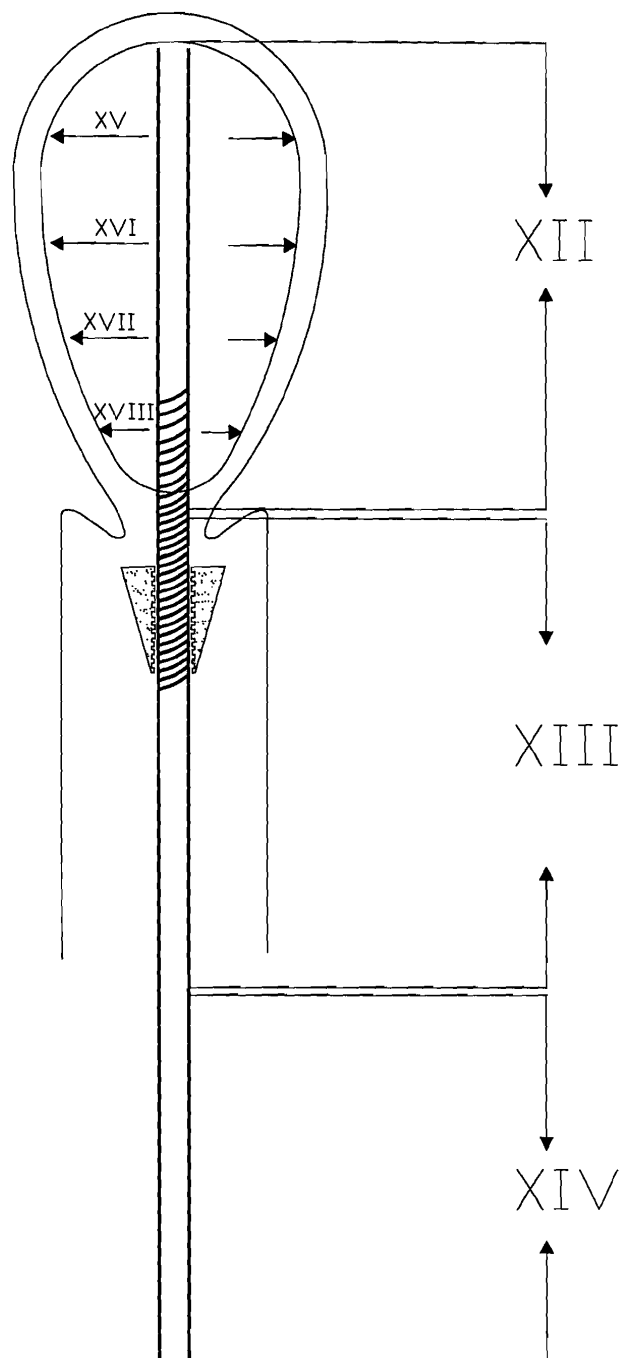
II - Co-attached Cervical Shutter "Barricade".

III - A Cross Sectional view of the Coaxial (2 Shafts) Balloon Catheter, where, IP refers to Inflation Port while DP refers to Drainage Port.



*Fig. 2:* Components & Approximate Measurements of Cervical Shutter "Barricade":

- IV - Length of Intrauterine Screw Modified Portion of the Balloon Catheter, (approximately 20mm).
- V - Length of the Intra Vaginal Screw Modified Portion of Balloon Catheter, (approximately 45mm).
- VI - Measure of Cervical Shutter Axial Length, (approximately 40mm).
- VII, VIII, IX, X - Approximate Measures of Cervical Shutter Outer Diameters at different Levels that Tapers Proximally and Widen Distally (30mm, 25mm 20mm,15mm respectively).
- XI - Measure of Outer Diameter of the Modified Screw Portion of the Balloon Catheter, (about 12mm).

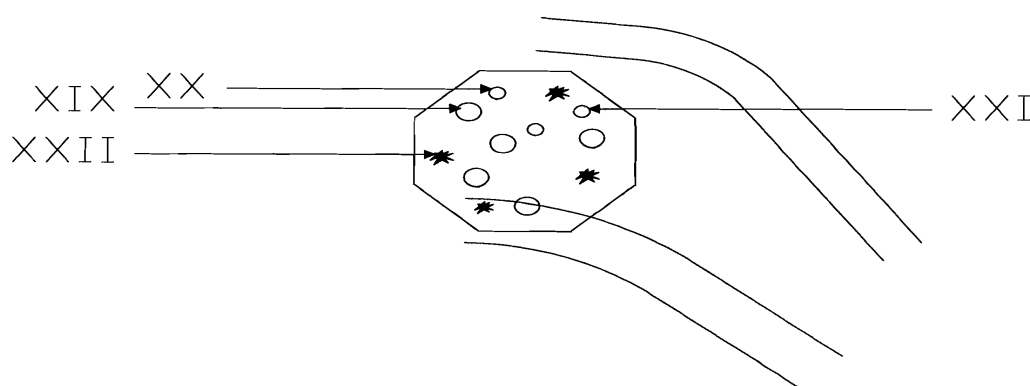


**Fig. 3:** Dimensions of the Different Portions of the TXA Coated Balloon and its Coaxial Catheter:

XII, XIII, XIV: Approximate Intrauterine, Intra Vaginal and Extra Vaginal Portions of the TXA Coated or Eluted Uterine Balloon (120mm, 110mm, 200mm respectively).

XV, XVI, XVII, XVIII: Approximate Transverse Diameters of the Inflated Balloon Inside Uterine Cavity that Tapers Proximally and Widen Distally to Conform to the Uterine Cavity (from above downwards: 80mm, 65mm, 50mm, 45mm respectively).





**Fig. 4:** Sketching an Illustrative View of Balloon Surface in Relation to the Uterine Wall and Demonstrating TXA Nano-particles Release from its Coating Matrix incorporating along with Liposomes, and or Polymers, and Excipients:

XIX: TXA Nano-particles.

XX: Drug Coating Matrix.

XXI: Liposomes.

XXII: Polymers & Excipients.

## CLAIMS

[0026]- Basically and specifically applicable to this invention and wherein said a TXA coated or eluted or medicated uterine balloon (an inflatable member with a proximal and distal ends and a working functional length ending in a stopcock and two way valve controlling the inflation and drainage ports) ,wherein said for use in post partumhaemorrhage (PPH), wherein, the outer layer of the balloon has been functionalized to serve to incorporate a matrix coating or eluting the anti-fibrinolytic, tranexamic acid particles or nano-particles for local release in the uterine cavity for that indication i.e. PPH. In this way, the currently used blank (non medicated or TXA uncoated) uterine balloons that are dependent solely on their tamponade effect could be replenished with adding the merits of topical application of anti fibrinolytic effect of tranexamic acid without the obligation of its systemic administration and its related theoretical risk of thromboembolism. Moreover, hereby, wherein said medicated or TXA coated or eluted uterine balloons, the medicament utilized is not restricted to tranexamic acid but is extended to include other haemostatic and coagulant medications like and not limited to thrombin, fibrinogen and activated recombinant factor seven (a FVII). Wherein said drug coating or eluting or other technologies utilized to functionalize balloons surface as delivery vehicle for a location (intra uterine), an indication (PPH) and a medication (TXA and other haemostatic) different from their currently used location, indication, and the released medications.

[0027]- As in claim 1, Wherein said drug coating or eluting utilized to functionalize balloons surface as delivery vehicle for a location (intra uterine), an indication (PPH) and a medication (TXA) different from

their currently used location, indication, and the released medications. wherein said TXA coated or eluted or medicated uterine balloon for use in PPH, and the outer coat of the uterine balloon is functionalized as a delivery vehicle for TXA and other allied coagulants and wherein said a back up mechanism against the fast egress of the released of the fore mentioned medications in utero, the cervical shutter "Barricade" described thereof can be the innovative serviceable back up mechanism. This cervical shutter is co attached with TXA coated or eluted uterine balloons so as to allow intrauterine retention of the drug and reasonable time for its action. The cervical shutter, "Barricade" is a specialized cone shaped (or any other shape that suits the vagina and can be easily manipulated intra vaginally) screw plug moving on the screw adapted intra vaginal portion of balloon catheter to shut the cervix at the cervico-vaginal junction .The cervical shutter serves not only to shut the cervix for a longer intrauterine TXA residency but also it therapeutically exert an additional counter pressure at the lower uterine segment (LUS), which may be the main site of bleeding as in cases of placenta praevia and abnormally adherent placenta.





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## Angular Pregnancy a Case Report

By Dr. Subashini, Dr. Nina V Kate, Dr. Madhuri Vasudevula  
& Dr. Jyothi Boble James

**Abstract-** Angular pregnancy though rare yet is an important entity since it is associated with complications during pregnancy and delivery such as persistent pelvic pain and bleeding, spontaneous abortion, uterine rupture, abnormal placental implantation, post partum hemorrhage and maternal death <sup>(1)</sup>. Due to lack of clinical understanding, angular pregnancy does not appear to be recognized as a clinical entity and, many cases are likely to go undiagnosed. Here we report a case of a 27 yr old primi who was referred to our hospital for termination of pregnancy in view of anomalous baby, presented with severe abdominal pain and vomiting after induction of labour. She underwent emergency laparotomy in view of threatened rupture and, surprisingly it turned out to be a conceptus of 20 wk angular pregnancy implanted in the right angle of the uterine cavity.

*GJMR-E Classification: NLMC Code: W 791*



*Strictly as per the compliance and regulations of:*



# Angular Pregnancy a Case Report

Dr. Subashini <sup>α</sup>, Dr. Nina V Kate <sup>σ</sup>, Dr. Madhuri Vasudevula <sup>ρ</sup> & Dr. Jyothi Boble James <sup>ω</sup>

**Abstract-** Angular pregnancy though rare yet is an important entity since it is associated with complications during pregnancy and delivery such as persistent pelvic pain and bleeding, spontaneous abortion, uterine rupture, abnormal placental implantation, post partum hemorrhage and maternal death <sup>(1)</sup>. Due to lack of clinical understanding, angular pregnancy does not appear to be recognized as a clinical entity and, many cases are likely to go undiagnosed. Here we report a case of a 27yr old primi who was referred to our hospital for termination of pregnancy in view of anomalous baby, presented with severe abdominal pain and vomiting after induction of labour. She underwent emergency laparotomy in view of threatened rupture and, surprisingly it turned out to be a conceptus of 20wk angular pregnancy implanted in the right angle of the uterine cavity. The fetus and placenta were extracted and, the uterus was repaired. Thorough understanding of angular pregnancy is must since its clinical findings and outcomes are different from other forms of ectopic pregnancy.

## I. INTRODUCTION

Angular pregnancy was first defined in 1898 by American Obstetrician Howard Kelly as "Implantation of an embryo just medial to the uterotubal junction and round ligament in the lateral angle of the uterine cavity"<sup>(2)</sup>. Angular pregnancy is potentially dangerous and may lead to complications during pregnancy and delivery such as persistent pelvic pain, bleeding, spontaneous abortion, uterine rupture, abnormal placental implantation, postpartum hemorrhage and maternal death <sup>(1)</sup>. The terms angular, interstitial, and cornual pregnancy have often been inappropriately interchanged. It is important to differentiate these terms as angular pregnancy can be followed up expectantly under close surveillance till term while interstitial and cornual pregnancies need to be terminated by medical or surgical methods <sup>(3,4,5)</sup>. An angular pregnancy is an eccentric intrauterine pregnancy with implantation of the embryo in the supero lateral angle of the uterine cavity. It results in asymmetrical enlargement of the uterus and lateral displacement of the round ligament. Angular pregnancy is perceived to be rare in medical literature, and <100 cases are reported. An interstitial pregnancy is an ectopic or extrauterine pregnancy which occurs when implantation is within the myometrium of interstitial part of the fallopian tube. Where as a cornual pregnancy is described when pregnancy occurs in one horn of a bicornuate uterus or septate uterus or in a rudimentary horn of a unicornuate uterus <sup>(4)</sup>.

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## II. CASE REPORT

A 27 yr old primigravida married since 1 yr was referred to our hospital at 20 wks of gestational age for termination of pregnancy in view of anomalous baby. Patient had a scan done at 6 wks of gestation which showed single intrauterine gestational sac with fetal pole and cardiac activity with healthy chorion. She reported of spotting PV at 8 wks of gestation for which she was started on oral progesterones and a repeat scan showed normal live fetus of 8 wks. She continued her pregnancy and an anomaly scan done at 19 wks of gestation revealed bilateral ventriculomegaly and then she was referred to our hospital for termination.

Bimanual examination revealed 20 wk uterus with cervix high up, os closed and no abnormal discharge.

After induction with mifepristone and misoprostol patient presented with severe abdominal pain and vomiting, her general condition was fair, and uterus was found to be tense and tender. On bimanual examination, anterior fornix was very deep, and the cervix was high up and could not be reached, post vaginal wall was lifted up like a septum through which presenting part was felt, and there was no abnormal discharge.

A decision for immediate laparotomy was taken in view of threatened rupture. Intraoperatively, the uterus was found to be asymmetrically enlarged and, no fetal parts were felt anteriorly, a right uterine angle was bulging with fetal parts and was buried into the POD lifting the posterior vaginal wall from below. The uterus was delivered out and the Right round ligament and tube were found to be displaced upwards and laterally, an incision was made in the bulging area, fetus and placenta extracted into too. There was a wide communication to the uterine cavity and, thin layer of myometrium could be seen, and this area started contracting and retracting. Square compression sutures were taken at the angle through the anterior and posterior walls to secure hemostasis and incision closed in 2 layers. Postoperative period was uneventful and, the patient was discharged on the 5<sup>th</sup> postop day. The Patient was reviewed after 15days and uterus was found to be normal size, mid position and, bilateral fornices free.



*Figure 1:* Image showing right angular Pregnancy with lateral displacement of round ligament



*Figure 2:* Intraop image showing fetus and uterus with right angle incision

### III. DISCUSSION

It is difficult to diagnose angular pregnancy with certainty and has to be differentiated from other abnormal implantation using sonography.

3d ultrasound and MRI can facilitate the diagnosis and reduce the possibility of diagnostic failure, evaluate the placental implantation anomalies and predict risk of uterine rupture.<sup>(6)</sup>

Specific criteria for diagnosing angular pregnancy were proposed by Jansen and Elliot in 1981 as <sup>(7)</sup>,

- 1) Clinical presentation with painful asymmetrical enlargement of uterus.
- 2) Directly observed lateral distension of uterus with or without rupture, accompanied by displacement of round ligament reflection laterally.
- 3) Retention of placenta in uterine angle <sup>(7)</sup>.

It was proposed by Grand et al, that surrounding endometrium is a specific sign. This sign is based on the hypothesis that, a double sac sign (a layer of decidual reaction and a chorionic ring) should be seen in angular pregnancy given its endometrial

implantation like other intrauterine pregnancies, while in interstitial pregnancy it is not seen as its location devoid of the endometrium<sup>(8)</sup>. Similar findings have been reported on MRI i.e. a gestational sac surrounded by hyperintense endometrium suggests an angular pregnancy, while a sac surrounded by T2 hypointense myometrium suggests an interstitial pregnancy<sup>(9)</sup>.

Angular pregnancies either terminate spontaneously or proceed to a potentially viable intrauterine pregnancy with significantly increased risk of complications during pregnancy and delivery. Jansen and Elliot reviewed 39 cases of angular pregnancies and reported a 38.5% chance of spontaneous or missed abortions and 13.6% chance of uterine rupture<sup>(7)</sup>. Which was updated Subsequently in 2014, with the addition of 46 cases, adjusting the estimates to 18% risk of spontaneous abortions & 28% risk of uterine rupture. The overall live birth rate was 25% but, those pregnancies managed expectantly and not terminated this rose upto 69 %.<sup>(10)</sup>

Management of angular pregnancy depends on the time of diagnosis, risk factors and desire for future pregnancies. Transvaginal ultrasound-guided, IM methotrexate injections (1mg/kg on day 1 & 3) in combination with folic acid inj intramuscularly, (0.1mg/kg on day 2 & 4) followed by operative hysteroscopy after 2 days to confirm collapsed sac, or by IM methotrexate (1mg/kg on day 0, 2, 4 and 6) in combination with IM folic acid ( 0.1mg/kg on 1, 3, 5 and 7) followed by diagnostic laparoscopy and hysteroscopy can be the options<sup>(11)</sup>.

Potential disadvantages of expectant management may include catastrophic complications such as uterine rupture. Baldawa et al, reported a case of angular ectopic pregnancy presenting as a ruptured lateral wall of the uterus<sup>(12)</sup>.

Based on patients choice expectant management of angular pregnancy can be chosen with proper, necessary counseling regarding natural courses, complications, need for close monitoring and frequent ultrasound. as a case of angular pregnancy treated by expectant management till 37 weeks, followed by repeat cesarean section with the delivery of healthy fetus weighing 3kg was documented<sup>(3)</sup>. The site of Angular pregnancy may be associated with uterine atony and inadequate contractions due to lack of myometrial tissue and increased bleeding due to excessive vascular development. In such case, square compressions suture through anterior and posterior wall to obliterate the asymmetrical uterine sacculation can be taken (1).

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# GLOBAL JOURNALS GUIDELINES HANDBOOK 2018

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# FELLOWS

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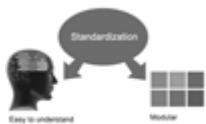
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- g) Suitable statistical data should also be given.
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**12. Know what you know:** Always try to know what you know by making objectives, otherwise you will be confused and unable to achieve your target.

**13. Use good grammar:** Always use good grammar and words that will have a positive impact on the evaluator; use of good vocabulary does not mean using tough words which the evaluator has to find in a dictionary. Do not fragment sentences. Eliminate one-word sentences. Do not ever use a big word when a smaller one would suffice.

Verbs have to be in agreement with their subjects. In a research paper, do not start sentences with conjunctions or finish them with prepositions. When writing formally, it is advisable to never split an infinitive because someone will (wrongly) complain. Avoid clichés like a disease. Always shun irritating alliteration. Use language which is simple and straightforward. Put together a neat summary.

**14. Arrangement of information:** Each section of the main body should start with an opening sentence, and there should be a changeover at the end of the section. Give only valid and powerful arguments for your topic. You may also maintain your arguments with records.

**15. Never start at the last minute:** Always allow enough time for research work. Leaving everything to the last minute will degrade your paper and spoil your work.

**16. Multitasking in research is not good:** Doing several things at the same time is a bad habit in the case of research activity. Research is an area where everything has a particular time slot. Divide your research work into parts, and do a particular part in a particular time slot.

**17. Never copy others' work:** Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.

**18. Go to seminars:** Attend seminars if the topic is relevant to your research area. Utilize all your resources.

**19. Refresh your mind after intervals:** Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.



**20. Think technically:** Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

**21. Adding unnecessary information:** Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

**22. Report concluded results:** Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

**23. Upon conclusion:** Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium through which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

## INFORMAL GUIDELINES OF RESEARCH PAPER WRITING

### Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

### Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

*The introduction:* This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

### The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

### General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

**To make a paper clear:** Adhere to recommended page limits.



### *Mistakes to avoid:*

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

### **Title page:**

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

**Abstract:** This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

*Reason for writing the article—theory, overall issue, purpose.*

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

### **Approach:**

- Single section and succinct.
- An outline of the job done is always written in past tense.
- Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

### **Introduction:**

The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.





*The following approach can create a valuable beginning:*

- Explain the value (significance) of the study.
- Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
- Briefly explain the study's tentative purpose and how it meets the declared objectives.

#### **Approach:**

Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done. Sort out your thoughts; manufacture one key point for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory specifically—do not take a broad view.

As always, give awareness to spelling, simplicity, and correctness of sentences and phrases.

#### **Procedures (methods and materials):**

This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

#### **Materials:**

*Materials may be reported in part of a section or else they may be recognized along with your measures.*

#### **Methods:**

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- Simplify—detail how procedures were completed, not how they were performed on a particular day.
- If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

#### **Approach:**

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

#### **What to keep away from:**

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings—save it for the argument.
- Leave out information that is immaterial to a third party.



**Results:**

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

**Content:**

- Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

**What to stay away from:**

- Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- Do not present similar data more than once.
- A manuscript should complement any figures or tables, not duplicate information.
- Never confuse figures with tables—there is a difference.

**Approach:**

As always, use past tense when you submit your results, and put the whole thing in a reasonable order.

Put figures and tables, appropriately numbered, in order at the end of the report.

If you desire, you may place your figures and tables properly within the text of your results section.

**Figures and tables:**

If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

**Discussion:**

The discussion is expected to be the trickiest segment to write. A lot of papers submitted to the journal are discarded based on problems with the discussion. There is no rule for how long an argument should be.

Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully described.

Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact, you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved the prospect, and let it drop at that. Make a decision as to whether each premise is supported or discarded or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."



Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work.

- You may propose future guidelines, such as how an experiment might be personalized to accomplish a new idea.
- Give details of all of your remarks as much as possible, focusing on mechanisms.
- Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- One piece of research will not counter an overall question, so maintain the large picture in mind. Where do you go next? The best studies unlock new avenues of study. What questions remain?
- Recommendations for detailed papers will offer supplementary suggestions.

#### **Approach:**

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

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BY GLOBAL JOURNALS

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Topics	Grades		
	A-B	C-D	E-F
<i>Abstract</i>	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
<i>Introduction</i>	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
<i>Methods and Procedures</i>	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
<i>Result</i>	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
<i>Discussion</i>	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
<i>References</i>	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring



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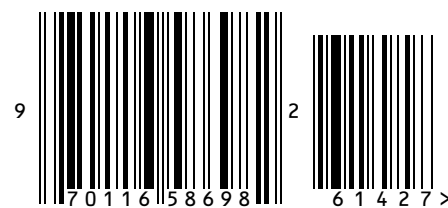
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