

A Hospital- Based Study about Antibiotic Therapy: Among Pregnant Women in the Third Trimester and in the Peripartum Period

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DOI: <https://doi.org/10.36347/sasjm.2025.v11i09.014>

| Received: 02.07.2025 | Accepted: 09.09.2025 | Published: 19.09.2025

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Abstract

Original Research Article

Antibiotics are one of the most commonly prescribed medicines for pregnant women. They have been extensively used during the previous years, which ultimately led to a panoply of undesirable and harmful side effects. Unfortunately, only few data have been collected concerning the use of antibiotics during the 3rd trimester of pregnancy and in the peripartum period. The available data are mostly collected out of monitoring networks because of the lack of studies that are conducted on those women. The present data concerning the safety of penicillin, cephalosporins, macrolides and quinolones with reference to the risk for preterm birth, low birth weight or even delivering children with small gestational age (SGA) are reassuring. So far, no study has shown a link between the gestational exposition to these antibiotics and the statistically- significant increase of the undesirable pregnancy risks. These harmful effects urge us to request the prescription of antibiotics and the recommendation of antibiotic therapy in general. Indeed, both in the cases of prelabor rupture membranes (PROM) and in the uterine revision the use of antibiotics has been proven inefficient, which suggests a restriction in their prescription in these two cases. More than half of the women who gave birth in our maternity center had consumed antibiotics during pregnancy, childbirth or in the post- partum period, which might explain the emergence of antibiotics resistance in our country.

Keywords: antibiotic therapy; pregnancy; peripartum; resistance.

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INTRODUCTION

The consumption of antibiotics is known to be the major cause of emerging resistances, especially in Tunisia where the level of antibiotics prescriptions and that of resistance are higher than in other countries [4]. The prescription of antibiotics during pregnancy and labor is due to the modifications occurring both within micro- organisms because of the maternal- fetal infections [5], and within the maternal microbic flora [6]. All these processes are most likely to result in an imbalance of the newborns' intestinal flora, which exposes them to gastrointestinal pathologies during childhood [7]. Such a distortion might also be followed by cerebral disorders such as epilepsy [8], OCD [9], allergies and asthma [10]. However, few are the data that have been collected concerning the use of antibiotics during the 3rd trimester of pregnancy and in the peripartum period. The available data are mostly collected out of monitoring networks because of the lack of studies realized upon the aforementioned women. The

present data concerning the safety of penicillin, cephalosporins, macrolides and quinolones with reference to the risk for preterm birth, low birth weight or even delivering children with small gestational age (SGA) are reassuring. So far, no study has shown a link between the gestational exposition to these antibiotics and the statistically- significant increase of the undesirable pregnancy risks [11-13]. These harmful effects put into question our prescription of antibiotics and the recommendation of antibiotic therapy in general. Accordingly, we have conducted a hospital- based study that aims at describing both the practice and the indications of antibiotic therapy during the 3rd semester of pregnancy, childbirth and in the postpartum period at the Maternity and Neonatology Center of Monastir (MNCM). Such a survey has enabled us to determine the indicators of the restriction of antibiotics' prescription.

Citation: Ouannassi Mounir, Korbi Asma, Montacer Hafsi, Marwen Ben Khelifa, Sana Bouakez, Amina Mnajja, Mosbahi Ataa, Belgaieb Ichrak, Zied Mokni, Rahma Ben Massara, Ameni Cherif, Hajjaji Awatef, Faleh Raja. A Hospital- Based Study about Antibiotic Therapy: Among Pregnant Women in the Third Trimester and in the Peripartum Period. SAS J Med, 2025 Sep 11(9): 898-905.

PATIENTS AND METHODS

Type of study:

A monocentric retrospective analytical observational and descriptive study conducted at the Maternity and Neonatology Center of Monastir (MNCM) for two months (September and October, 2020).

The research Population:

Our study had included every woman with a full-term pregnancy (starting from 28 weeks of amenorrhea) admitted for delivery into the Gynecology Department at the Maternity and Neonatology Center of Monastir. We have also included women who haven't taken antibiotics neither during pregnancy, nor in childbirth, not even in the postpartum period. Before proceeding to the data gathering, we have conducted this study on 400 women which is the minimal sampling number. During the 2 months of our study, we have also gathered information from 502 files of clinical observation.

Data gathering:

The patients have been identified from the data provided by the Medical Information Systems Program of our center. The identified patients' medical files have been consulted afterwards in order to collect the data. This procedure has been conducted anonymously. The data gathered include:

- **The patients' characteristics:** age, weight, size, body mass index (BMI), parity, medical-surgical history, smoking, prenatal care, admission cause
- **Ultrasound examinations:** liquid volume and estimated fetal weight
- **Delivery process:** full-term labor, types of birth delivery (natural, induced, scheduled Cesarean)
- **Biological data:** the carriage of Streptococcus B, the results of blood and urine samples
- **Antibiotic therapy:** the notion of allergy, chronology, indications, and the molecules taken.
- Maternal and neonatal clinical evaluation in the postpartum period

Statistical study:

Data were entered, coded and analyzed using Statistical Package for Social Science (SPSS) software (the 25.0 version) at the UHC "Fattouma Bourguiba" Maternity Department in Monastir. The descriptive study of the qualitative variables was conducted using the registered rates and frequencies (%). On the other hand, in the analytical study we used the Pearson chi2 test to compare two frequencies in the case of verified application conditions, but we used the Fischer chi2 test in the opposite case.

Some correlations between the use of antibiotic therapy and several maternal characteristics have been investigated, such as gravidity (parity), the estimated date of delivery, gestational diabetes and the carriage of Streptococcus B.

Ethical considerations:

The protocol that we followed along our survey abides by the Scientific Research ethics. We obtained an informed consent from the Monastir Medical School Thesis Committee.

RESULTS

Epidemiological data: 97.8 % of the female patients included in our study (491) were older than 20 years. The morphological evaluation has shown that 297 of parturient women were obese (59.2%), 194 were of normal size (38.6%) and 11 were skinny (2.2 %). 43 women proved to have had a medical and/ or surgical history (86 %): diabetes (1.8%), hypothyroidy (1.4%), hepatitis B (0.8%), high blood pressure (0.4%), thrombophilia (0.2%), appendicitis (3.8%) and cholecystectomy (0.8%). Primigravida women represented 28.3% of cases (n= 142). From a total of 360 non-primigravida women, 107 women have given birth before by Caesarean section. 11 women (2.2%) presented a history of gynecological obstetrical pathologies: Upper Genital Tract Infections (0.8%), Ectopic Pregnancy (0.6%), cystectomy (0.6%) and breast abscess (0.2%). 46 women (9.2%) were the subject of previous gynecological interventions like inspiration (8%), laparotomy (1%) and laparoscopy (0.2%).

The course of pregnancy: 421 women (83.9%) followed a right prenatal care which is defined by at least 6 visits to the obstetrician starting from the 4th month of pregnancy. 195 (38.8%) have undergone at least one pregnancy complication: anemia (33.3%), gestational diabetes (12.5%), gestational hypertension (6.6%), preeclampsia (3.2%) and thrombophilia (3.2%). 28 women (5.6%) have been prescribed antibiotic therapy during the 3rd trimester of their pregnancy to treat either acute pyelonephritis among 10 patients (2%), prelabor rupture of membranes (PROM) for 9 patients (1.8%), isolated fever for 7 patients (1.4%), Covid-19 for a single case or erysipelas for one single case too.

Causes of admission: The three major causes for the patients' admission were pelvic pain (64.5%), vaginal discharge (15.7%) and induction of labor (6.2%). The decreased fetal movements had led 3 women to seek medical advice in our department prior to their admission (0.6%). Patients with full-term pregnancy represented 90% of the total admission cases (n= 452), those with pre-term pregnancy represented 6.6% (n=33) and the ones with post-term pregnancy represented 3.4% of the total cases (n=17).

The stages of labor: The dilation of the cervix was in the active stage among 34 women (6.8%) in the labor room.

The amniotic sac was ruptured among 132 women (26.3%): about 10 patients (2%) had a tinted amniotic fluid, and 2 others (0.4%) had a meconium- stained one. A prelabor rupture of membranes (PROM) exceeding 12 hours was observed among 79 women. It occurred prematurely in 9 cases (2%), and in a pregnancy term equal to or greater than 37 weeks in 57 ones (11.6%). 66 women (83.6%) among those who experienced a prelabor rupture of membranes exceeding 12 hours (79) had been prescribed an antibiotic therapy. The FHR (Fetal Heart Rate) was reassuring in most cases before labor (95.8%). The amount of the amniotic fluid decreased among 152 women (30.3%). During childbirth, labor was spontaneous in 73.7% of the cases (n= 370), and artificially induced in 26.3% of the cases (n= 132) with a normal rate (50.8%), a slow rate (17.1%) or a quick rate (15.7%). The patients who had a vaginal delivery represented 71.7% of cases (n=360) and those who had birth by caesarian section represented 28.3% of total cases (n= 142). The forceps was used among 11 women (3%) who had a vaginal delivery. The epidural anesthesia was used only for 2 women from those who had birth by caesarian section. In 25 cases of Acute Fetal Distress (AFD) childbirth by caesarian section was indicated. In the prepartum period, we signaled a tachycardia among 4 women (0.8%) and a febrile and subfebrile state for one single patient (0.2%). The neonatal weight was normal and comprised between 2500 and 4000 gr in 82.7% of cases. A hypotrophy was signaled among 26 newborns (5.2%), and a macrosomia was noticed among 61 others (12.2%).

Antibiotic therapy: Nine women were allergic to penicillin (1.8%). The prescription of antibiotics was indicated for 301 female patients (60%). Their intake varied across the pregnancy and after childbirth: the 3rd trimester of pregnancy represented 9.3% of the total indications, the prepartum period represented 46.1% and the postpartum one represented 56.1%. Penicillin

(amoxicillin- clavulanic acid, ampicillin and amoxicillin) were actively administrated for our patients (58%). In case of allergy, we resorted to clindamycin and to macrolides following the department's protocol. The three major indications for antibiotics prescription were childbirth by caesarian section (42.9% of total indications), uterine revision (28.2%) and PROM (21.9%).

Biological samples: The biological results have revealed a hyperleukocytosis in 8.2% of total cases and a positive CRP test among 12.7% of patients. The cytobacteriological urine test (CBUT) conducted upon 102 patients (20.3%) was positive in 7.8% of total cases. The vaginal swab conducted upon 98 patients (19.5%) was positive among 10 women, and streptococcus was isolated in each of these samples. The amniotic fluid sampling realized upon 5 patients was negative.

The postpartum period: Some complications were observed among 16 patients (3.2%) notably uterine rupture among 11 patients (68.8%), hemorrhage (18.7%) and uterine atony (12.5%). We resorted to blood transfusion for 8 women (1.6%). 3 women (0.6%) were sent to the intensive care unit right after childbirth. One single woman had Covid-19 with no serious or dangerous symptoms but had to be sent to the Covid19 special unit.

Statistical analysis: The frequency of antibiotics prescription was significantly higher among primigravida women (OR=1,72; IC95% [1,1-1,46]) right after premature childbirth (OR=1,5; IC95% [1,3-1,75]) where PROM exceeds 12 hours (OR=1,87; IC95% [1,7-2,05]) and with a decreased amount of amniotic fluid (OR=1,91; IC95% [1,27-2,87]). The antibiotics prescription was indicated in each birth by caesarian section (OR=2,26; IC95% [2,01-2,54]) with the presence of biological inflammatory syndrome (BIS).

Table 1: Epidemiological characteristics of the research population

	Number (n)	Percentage (%)
Age		
< 20 ans	11	2,2
≥ 20 ans	491	97,8
BMI		
Skinny	11	2,2
Normal	194	38,6
Obese	297	59,2
Medical- surgical history (n=43)		
Diabetes	9	1,8
Dysthyroidy	7	1,4
Hepatitis B	4	0,8
HBP	2	0,4
Thrombophily	1	0,2
Appendectomy	19	3,8
Cholecystectomy	4	0,8
Gravidity		
Primigravida	142	28,3
Multigravida	360	71,7

History of gynecological pathologies (n=11)		
UGTI	4	0,8
Ectopic Pregnancy	3	0,6
Cystectomy	3	0,6
Breast abscess	1	0,2
Gynecological interventions (n=46)		
Aspiration	40	8
Laparotomy	5	1
Laparoscopy	1	0,2

Table II: Data concerning the course of pregnancy within the research population

	Number (n)	Percentage (%)
Prenatal care		
Regular	81	16,1
Irregular	421	83,9
Complications (n=195)		
Anemia	167	33,3
Gestational Diabetes	63	12,5
Gestational Hypertension	33	6,6
Preeclampsia	16	3,2
Thrombocytopenia	16	3,2
Antibiotic therapy (n=28)		
Acute Pyelonephritis	10	2
PROM (> 12h)	9	1,8
Isolated fever	7	1,4
COVID-19	1	0,2

Table III: Stages of Labor among the research population

	Number (n)	Percentage (%)
Admission causes		
Pelvic pain	324	64,5
Vaginal discharge	79	15,7
Induction of labor	31	6,2
Decreased fetal movements	3	0,6
Others	65	12,9
Term		
Pre- partum	33	6,6
Full- term	452	90
Post- partum	17	3,4
Amniotic sac		
Intact	370	73,7
Ruptured	132	26,3
Fundal Height		
Decreased	31	6,2
Normal	347	69,1
Increased	124	24,7
Dilation of cervix		
Pre- labor phase	468	93,2
Active phase	34	6,8
Prelabor FHR		
Reassuring	481	95,8
Not reassuring	21	4,2
FHR during labor		
Normal	480	95,6
Deceleration	14	2,8
Tachycardia	2	0,4
Undone	6	1,2

Amount of the amniotic fluid		
Decreased	152	30,3
Normal	343	68,3
Increased	7	1,4
Labor		
Spontaneous	370	73,7
Induced	132	26,3
Normal	255	50,8
Slow	86	17,1
Quick	79	15,7
Types of childbirth delivery		
Caesarian section	142	28,3
Vaginal delivery without manœuvres	349	69,5
Vaginal delivery with manœuvres	11	0,6

Tableau IV: Criteria for antibiotics prescription

	Pas d'ATB (n=201)	ATB (n=301)	P	OR	IC95%
Maternal age					
< 20 years	6 (3%)	5 (1,7%)	0,245	-	-
≥ 20 years	195 (97%)	296 (98,3%)			
Parity					
Primigravida	47 (23,4%)	111 (36,9%)	0,001	1,272	[1,107-1,462]
Multigravida	154 (76,6%)	190 (63,1%)			
Obesity	110 (54,7%)	188 (62,5%)	0,084	-	-
Pathological history					
Allergy to penicillin	5 (2,5%)	4 (1,3%)	0,266	-	-
Gestational Hypertension	12 (6%)	21 (7%)	0,656	-	-
Medical history	8 (4%)	15 (5%)	0,598	-	-
Surgical history	7 (3,5%)	17 (5,6%)	0,265	-	-
Labor					
Premature	4 (2%)	29 (9,6%)			
Full- term	197 (98%)	272 (90,4%)	0,003	1,515	[1,306-1,757]
Beginning of labor					
Spontaneous	171 (85,1%)	199 (66,1%)	0,014	2,15	[1,157-3,995]
Induced	30 (14,9%)	102 (33,9%)			
RPOM > 12h	1 (0,5%)	78 (25,9%)	0,001	1,87	[1,706-2,05]
Decreased amniotic fluid	156 (77,6%)	194 (64,5%)	0,002	1,912	[1,273-2,873]
Macrosomia	21 (10,4%)	40 (13,3%)	0,340	-	-
Types of childbirth delivery					
Caesarian section	0 (0%)	142 (47,2%)	0,000	2,264	[2,016-2,543]
Vaginal	201 (100%)	159 (52,8%)			
CBUT+	0 (0%)	8 (8,2%)	0,718	-	-

DISCUSSION

In all cases, antibiotics prescriptions has significantly increased in the past years. This is manifested in a study conducted by Broe and al. upon 987973 patients who had given birth in Denmark between 2000 and 2010. The research showed that the level of antibiotics prescriptions increased from 28.4 % in 2000 against 37% in 2010 [11]. This increase might lead to fears of an outbreak of antibiotic resistance along with neonatal side- effects that result from microbiota modification such as obesity [12], asthma and allergies [7], and even OCD's (6). More than half of the women included in our study have taken at least one type of

antibiotics starting from week 28 of pregnancy. About one third of them have also taken antibiotics during labor, whereas half of them in both pre partum and postpartum periods, but only 10% of them took antibiotics immediately in the postpartum period. We shall note that the antibiotics' prescription in our study follows a measurement procedure published by Clothilde Petitnicola and al. in France in 2016 which reveals that the frequency rate of antibiotic therapy prescriptions is 56% during pregnancy [13]. Some indications were frequently observed in these prescriptions. Antibiotic therapy was used to treat urinary tract colonization in pregnancy and urinary tract infection, in order to prevent

the risk of pyelonephritis and ultimately the birth of newborns less than 2500g of weight [14]. Urine tract infections represented 1.6 % of total cases, a rate comparable to those in literature (1 and 2%) [12]. New recommendations in antibiotic therapy stipulate that Cefotaxime is the accurate molecule to treat Acute Pyelonephritis APN in pregnancy. In 2013 Cochrane has shown that in the case of PROM, maternal antibiotic therapy leads to a prolongation of pregnancy and to a decrease in the risks of neonatal mortality, with no long-term harm to children [15]. Antibiotic prophylaxis has to be undertaken while awaiting the vaginal swab culture in order to adjust the medical treatment for the isolated germ [16]. This procedure has been approved of in many studies to which Kenyon and al. have realized a metanalysis [17]. While awaiting the bacteriological results, the medical treatment has to start by the intake of amoxicillin (1g/ 8h, intravenously) or 3rd generation cephalosporin (cefotaxime: 1g/ 8h). If the culture results are negative, the treatment has to be stopped. However, if the results are positive, antibiotic therapy has to be pursued for 5 days and the medical treatment has to be adapted for the isolated germ [18]. Our department has respected this procedure in the case of PROM by following an amoxicillin clavulanic- acid treatment. Generally, the carriage of Streptococcus B is evaluated between 8 and 20 % according to categories [9]. This rate was 9.1% in our study, comparable to that found in France (11 to 15.4%) (9). In our study, 3 patients were suspect of carrying chorioamnionitis in the peripartum period, which resulted in two operative vaginal deliveries and one delivery by caesarian section, both urgently undergone in order to minimize the fetal extraction time. Accordingly, our department followed a protocol based on triple antibiotic therapy (Cefotaxime, Gentamicin and Metronidazole) targeting anaerobic germs, Streptococcus B and Mycoplasma Genitalium. The American College of Obstetricians and Gynecologists recommend, however, another protocol based on a dual antibiotic therapy (Ampicillin and Gentamicin). Right after deliveries by Caesarian section, the antibiotic prophylaxis of the surgical site is crucial in the prevention of potential maternal infectious complications [19, 20]. Indeed, the risk of infections in the postpartum period right after deliveries by caesarian section is very high since its postsurgical infection rate is higher than that of any other surgical interventions [21-23]. Accordingly, the French Society of Anesthesiology and Intensive Care SFAR considers that the risk of infection right after scheduled or urgent delivery by caesarian section is high, and stipulates that the use of antibiotic prophylaxis reduces this risk by half (24). It is recommended to inject an antibiotic 30 mins prior to the incision and not after the umbilical cord clamping [24]. According to the protocol followed by our research department, the antibiotic prophylaxis is done through the administration of 2g IV of Cefazolin at the time of incision, which suggests a 30-minute delay compared to the SFAR recommended protocol. Recent studies have also suggested that the use of antibiotic prophylaxis

within a more extended spectrum might reduce the risk of post- caesarian infections compared to the standard narrow intake of antibiotic prophylaxis administrated right after the umbilical cord clamping [25 -27]. Some maternal factors might also affect the frequency of antibiotics prescriptions. In our study, 70% of primigravida women have taken at least one type of antibiotics against 50% of multigravida women. Similar results were found in the study conducted by Clothide Petitnicola and al. in France in 2016, which reveal a frequency rate of 62.7% among primigravida women against 50.8% among multigravida women with an OR= 2.2 [13]. The same study also showed that 57.7% of patients with gestational diabetes had received antibiotics almost comparable to the other patients' category [13]. Nevertheless, the rate of antibiotics prescription in our research was significantly higher among patients with diabetes (79.4%). In cases of premature childbirth, this level was comparable to that found in the study conducted by Clothide Petitnicola and al. [13], respectively equal to 87.9% and 90%. Also, in cases of labor induction, this level was equal to 60% in our study against 77% in the French one [13]. The increase of the antibiotics prescriptions clearly results in the increase of bacterial resistances to antibiotics [28]. Accordingly, Wilkie and al. shows in an American study conducted in February, 2019, that the resistance of Escherichia coli to ampicillin was detected in 81% of samples, which is higher than the antibiogram data of 2016 (53%) and those of 2011 (51%). The frequency of broad- spectrum beta- lactamases resistance has also increased, moving from 3 to 48% [68]. The changes occurring in the E. coli resistance to antibiotics between past and present are also to be highlighted. The possible explanation for such results is the increased consumption of antibiotics during pregnancy [68]. As a result, the WHO and recently (2016) the ACOG no longer recommend antibiotic therapy in cases of PROM in full-term pregnancy [20] with the exception of the carriage of Streptococcus B. They rather suggest a labor induction by oxytocin, without increasing the risk of caesarian section [29]. Uterine revision represented 16.9% of total antibiotic therapy indications, ranked as 2nd following PROM. Ampicillin is the accurate molecule to be administrated in the postpartum period with a 2g/ 6h dose. This prescription follows the WHO present recommendations set in 2015 [20], despite the presence of any tangible proof due to the absence of published research. In order to prevent the antibiotic therapy prescriptions abuse, other references are undoubtedly more accurate. Indeed, a positive systematic Streptococcus B screening test followed by an antibiotic prophylaxis during childbirth is still debatable, since some parties are still advocating the use of an antibiotic-therapy- based strategy to defeat risks [15, 30, 31].

In front of the emerging increase of antibiotic resistance, our research ultimately suggests to stop or at least to reduce this increase by the decrease of antibiotics' prescriptions.

CONCLUSION

Our study has demonstrated that more than half of the women who gave birth in our center of maternity had taken antibiotics during their pregnancy, childbirth and in the post- partum period. This high consumption of antibiotics has probably resulted in the emergence of antibiotic resistance in our country. The indications for antibiotics that might be reduced are the PROM and uterine revision, to which antibiotics have proven to be inefficient.

List of abbreviations

Prelabor rupture membranes (PROM)

small gestational age (SGA)

the Maternity and Neonatology Center of Monastir (MNCM)

body mass index (BMI)

Statistical

Package for Social Science (SPSS)

The cytobacteriological urine test (CBUT)

biological inflammatory syndrome (BIS)

treat Acute Pyelonephritis (APN)

Ethics approval and consent to participate

The research was carried out in compliance with Good Clinical Practice conditions, adhering to the ethical standards collections. Furthermore, all procedures were performed in alignment with applicable guidelines and regulations. informed consent to participate was obtained from all of the participants in the stud prior to their inclusion in the research. Measures were taken to safeguard the privacy and confidentiality of the research participants' personal information. Additionally, the Faculty of Medicine's Ethical Committee, affiliated with the University of Monastir, Tunisia, granted approval for the study.

Consent for publication:

This manuscript does not contain any individual person's data in the form of image or video. Hence consent for publication is not applicable.

Availability of data and materials

The datasets and materials used during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors do not have any conflicting interests to declare

Funding: There was no funding for this work.

Acknowledgement

We would like to express our sincere gratitude to the staff of the Maternity and Neonatology Center of Monastir for their valuable assistance in data collection and patient care throughout the study. Our thanks extend to the Medical Information Systems Program team for facilitating access to the necessary clinical records. We also acknowledge the support of the Ethics Committee of

the Monastir Medical School for their guidance and approval of this research. Finally, we are deeply grateful to the patients who agreed to participate in this study, making this research possible.

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