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## Original Article

# Compliance with national guidelines for antibiotic prophylaxis prescription with a surgical abortion: Results of the Mya study



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## ABSTRACT

**Purpose:** Performing an antibiotic prophylaxis (ATBP) with a surgical abortion (SA) is recommended in numerous countries, including France where the CNGOF has issued guidelines. There is little data regarding the actual application of these guidelines in clinical practice. The aim of this study was to evaluate the practice of ATBP with SA and to assess the degree of compliance with the national guidelines. **Methods:** This longitudinal, prospective, multicenter, non-interventional study was undertaken between December 2013 and July 2014 with the objective of assessing the modalities of prescription of ATBP under real-life conditions in the setting of SA, and to compare it with the national guidelines.

**Results:** A total of 542 pregnant patients agreed to participate and were included by 36 French hospitals. Of these 36 active centers, 18 (50%) systematically prescribed an ATBP, while 10 (27.8%) prescribed an ATBP depending on the risks for the patient. Of these 542 patients, 263 (48.5%) received an ATBP prescription, 274 (50.6%) did not receive such a prescription. The prescribed ATBP was metronidazole (88/263 (33.5%)), azythromycin (76/263 (28.9%)), or doxycycline (44/263 (16.7%)). In total, 208/263 (79.1%) of the patients received an ATBP. Finally, three factors were identified as independent contributors that influence the prescription of an ATBP: the prescribed cervix preparation, the type of center, and the number of surgical abortions per year in the center over 500/year.

**Conclusion:** Only half of the patients who undergo an SA receive a prescription for ATBP. Of the prescribed antibiotics, 80% correspond with the recommended ones.

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## Introduction

The risk of infection with surgical abortion (SA) is low. Depending on the selected criteria, this risk is between 0.01 and 2.44% [1–3]. With certain types of microorganism, these infections can sometimes be quite serious, although the main complication from infection after SA is the risk of pelvic infection in light of its effects on fertility [4–7]. Consequently, several learned societies recommend systematically performing an antibiotic prophylaxis (ATBP) with SA [8–12]. In 2012, the French National College of Obstetric Gynecology [12] released guidelines that recommend systematic ATBP with SA. For those under 25 years of age or if there are risk factors for STD the recommended ATBs are doxycycline or azithromycin. The doses of doxycycline

recommended are a single dose of 100 mg one hour before the abortion followed by 200 mg immediately after the procedure. Azithromycin 1 g is an interesting alternative particularly in the case of intolerance to doxycycline [12]. Over 25 years of age, in the absence of risk factor of STD, the recommended ATB is metronidazole 500 mg at the time of the abortion followed by 500 mg four hours and eight hours after [12].

In 2014, we carried out a survey of the practice of SA to investigate the conditions for performing SA and particularly the cervix preparation [13]. One of the objectives of this survey was to evaluate whether the guidelines of the CNGOF for ATBP are applied in clinical practice and what the factors are that influence performing an ATBP.

## Materials and methods

A longitudinal, prospective, multicenter, non-interventional study was undertaken between December 2013 and September

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2014 for which the main objective was assessment in real-life conditions of the modalities of the cervical preparation prior to the surgery. To evaluate the representativeness of the selected centers and the others in term of activity and demographic environment, we made a comparative analyses between the two groups which confirmed these 36 centers were representative of the 138 centers (13). To evaluate the representativeness of the selected centers and the others in term of activity and demographic environment, we made a comparative analyses between the two groups which confirmed these 36 centers were representative of the 138 centers (13). Evaluation of the performance of an antibiotic prophylaxis for a surgical abortion was among the secondary objectives of this study.

#### Participating centers

The eligible centers for this study were French public and private hospitals with at least 50% of their activity allocated to surgical abortions and that performed more than 100 abortions per year. Eligible centers were selected from the SAE (Establishments Annual Statistics) database containing the most recent information for activity in France. In total, out of 138 centers identified that performed surgical abortions in their daily routine, 36 centers agreed to participate and they included at least one patient. Of these 36 centers, 18 (50%) were university public hospitals, 11 (30.5%) were non-university public hospitals, and 7 (19.5%) were private hospitals or other facilities. These 36 active centers had a median rate of inclusion of 16 patients (2–20). Included centers were representative in terms of activity and demographic environment [13]. The intention was to include up to 20 patients. For each center, the collected data comprised: the number of surgical abortions per year, the type of cervical preparation.

#### The study population

The criteria for eligibility were patients who were 18 years of age or older who underwent a surgical abortion according to the French legal conditions (i.e. a pregnancy with less than 14 weeks of amenorrhea) and who did not have serious medical conditions, contraindications to surgical abortion and/or to the anaesthesia, or memory/cognitive disorders. The eligible women were informed of all of the aspects of the study (oral and written information) before confirming their willingness to participate. The exclusion criteria for the analyses comprised situations where patients changed their minds (i.e. continuing pregnancy) or when they were lost to follow-up before the surgery. For each patient, the recorded variables were the demographic and clinical characteristics, prior obstetrical issues, the term of the abortion, the prescription of an antibiotic prophylactic, and the type of antibiotic prescribed.

The calculated number of patients needed was 560 to obtain a 5% level of accuracy in the estimation of the proportions and with a proportion of 50% and assuming a statistical power of 80%, with a 5% significance level taking into account the risk of loss to follow-up. The prescription of an ATBP (or the lack thereof) was indicated on the day of inclusion in the study.

This study was approved by the Advisory Committee for Data Processing in Health Research (CCTIRS) and it received authorization from the French Data Protection Authority (CNIL).

#### Statistical analysis

For quantitative variables, the mean, standard deviation, median, and range were analysed. For qualitative variables, the rate and the percentage were reported.

A logistic regression model was also generated to identify factors associated with ATBP prescription (yes/no). In a first univariate analysis, we explored different potential explanatory variables:

patient age, professional situation, parity, gynecological history (e.g. conization, salpingitis, and history of gynecological surgeries), the number of previous pregnancies, previous induced abortions, gestational age (by groups), the woman's age (by groups), the number of abortions performed by the center ( $\pm 500$  yearly), the type of center (i.e. university public hospital, public hospital, private hospital, or other), and the mode of anesthesia (local/general). We determined the necessary sample size to observe a precision of 5% in the estimation of the proportions and with a reference proportion of 50% and assuming a statistical power of 80%, with 5% significance level. The aim was then to recruit around 400 patients, but considering 40% of lost to follow-up during the two successive visits, we increased the sample size by 40%, leading to 560 patients to include. Assuming that the study involves 40 active centers, this corresponds to 15 patients per center to recruit on average.

Variables with p-values of less than 0.25 were included in a multiple logistic model. A selection was then performed among the adjusted variables (suppression of variables when the overall p-value was greater than 0.05). Data management and statistical analyses were performed using the SAS software program (version 9.1, SAS Institute, North Carolina, USA).

#### Results

All up, 542 patients were included over the study period. Out of the 542 patients, 263 (48.5%) received a prescription for an ATBP, 274 (50.6%) did not receive this, and this data was missing for 5 patients (0.9%). The prescribed ATBP was metronidazole (88/263 (33.5%)), azythromycin (76/263 (28.9%)), doxycycline (69/263 (26.2%)) or a different antibiotic in 4 cases (1.5%), while this data was not available for 26 cases (9.9%). All up, 208 of the patients received a prescription for an antibiotic recommended by the 2012 guidelines of the CNGOF, or 208/263 (79.1%) of the patients who had received an ATBP.

Selection of the variables allowed a final model to be obtained with the following explanatory variables: the prescribed cervix preparation, the type of center, and the number of surgical abortions per year in the center over 500/year. The age of the patient and the occurrence of a prior pregnancy are enforced in the model. The patients for whom there was a missing value for one of the variables included in the model were excluded from the analyses, thereby yielding 429 patients who were analyzed. Of these patients, 207 had an antibiotic prophylactic prescription at inclusion (48%) (Table 1).

#### Discussion

A Cochrane review of the literature in 2012 evaluated the efficacy of ATBP for limiting the risk of infection, as well as the most efficacious protocol and strategy (e.g. a systematic ATBP or depending on the risk) [14]. Out of the 15 selected randomized studies versus placebo, it found an effect of ATBP on the risk of pelvic infection (RR of 0.59, with a 95% confidence interval from 0.46 to 0.75) [14]. The data, however, were not enough to retain a specific protocol or strategy. We selected centers which have experience of both methods of abortion.

The majority of learned societies favor systematic ATBP [8–12]. The proposed protocols differ, however. The 2012 recommendations of the CNGOF regarding antibiotic prophylaxis are still in effect, with systematic ATBP using doxycycline or azithromycin for women of less than 25 years of age or when there are risk factors for STDs, and metronidazole for those over 25 years of age and the absence of risk factors for STDs [12]. In our study, only 263/542 (48.5%) patients had an ATBP prescription. For the patients who had an ATBP, 208/263 (79.1%) cases was the antibiotic in fact what is recommended by the guidelines. Even if ATBP has proven its

**Table 1**  
Results of the multivariate multinomial logistic regression.

	N (%) Total: 429	OR	95% CI		p
<b>Nature of the prescribed treatment</b>					< <b>0.001</b>
Mifepristone	156 (36.4%)	1			
Mifepristone + Misoprostol	89 (20.8%)	2.357	1.300	4.275	
Misoprostol	184 (42.9%)	2.750	1.595	4.741	
<b>Nature of the center</b>					< <b>0.0001</b>
UHC <sup>a</sup>	289 (67.4%)	1			
Other	45 (10.5%)	0.931	0.444	1.950	
HC-GHC <sup>b</sup>	61 (14.2%)	73.472	16.811	321.111	
Private clinic	34 (7.9%)	8.415	1.940	36.509	
<b>Number of SA<sup>c</sup> undertaken at the center</b>					< <b>0.001</b>
Less than 500/year	84 (19.6%)	1			
More than 500/year	345 (80.4%)	10.033	2.803	35.907	
<b>Age of the patient</b>					<b>0.82</b>
18–24 years of age	174 (40.6%)	1			
25–34 years of age	170 (39.6%)	0.854	0.506	1.441	
35 years of age and over	85 (19.8%)	0.965	0.497	1.875	
<b>Occurrence of a prior pregnancy</b>					<b>0.21</b>
No	164 (38.2%)	1			
Yes	265 (61.8%)	0.720	0.433	1.198	

<sup>a</sup> UHC: University Hospital Center.

<sup>b</sup> HC-GHC: Hospital Center- General Hospital Center.

<sup>c</sup> SA: Surgical Abortion.

efficiency the kind of protocol couldn't be chosen [12]. There have been a few studies of the efficacy of ATBPs [12]. The implementation of a course of ATBP prior to the SA requires modification of the protocols by the centers and adherence by the entire team. Given that the risk of infection is low and that it is often not managed by the initial treatment center, it is hard to generate awareness by the teams of the risk. Lastly, the survey started a year after the release of the guidelines, which may be too soon to evaluate the uptake of these recommendations.

The prescription of an ATBP was more likely in case of cervical preparation with misoprostol only or in association with mifepristone relative to mifepristone only. The characteristics of the patient, such as their age and the occurrence of a prior pregnancy in particular, were not factors influencing the prescription of an ATBP. An ATBP was more likely to be prescribed when a center that performed more than 500 SA/year and when a public non-university center was involved (see Table 1). The centers that perform cervical preparations with mifepristone-only also prefer that no medications are taken the day of the SA. In these centers, it is likely that the implementation of an ATBP procedure requires modification of the protocols. The centers that had a level of activity exceeding 500 SA/year prescribed more ATBPs. It is likely that the centers that have higher rates of SA procedures are more aware of the risks of infection given that such cases are presumably more frequent at these centers with high rates of the procedure. ATBP are prescribed more often in general hospitals relative to university hospitals and clinics.

In conclusion, the recommendations for ATBP by the CNGOF with SA were followed by half of the centers, and slightly less than half of the patients in the study had an ATBP. Of the prescribed ATB, approximately 80% were ATB recommended by the guidelines in effect. Although not linked to the characteristics of the patient or the pregnancy, the factors influencing the prescription of ATB were linked to the nature of the centers.

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## Declaration of interest statement

One author is a member of the Scientific Board of Exelgyn. None of the other authors have a conflict of interest to declare.

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