Risk of Ionizing Radiation in Women of Childbearing Age undergoing Radiofrequency Ablation


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Abstract

Background: The International Commission of Radiology recommends a pregnancy screening test to all female patients of childbearing age who will undergo a radiological study. Radiation is known to be teratogenic and its effect is cumulative. The teratogenic potential starts at doses close to those used during these procedures. The prevalence of positive pregnancy tests in patients undergoing electrophysiological studies and/or catheter ablation in our midst is unknown.

Objective: To evaluate the prevalence of positive pregnancy tests in female patients referred for electrophysiological study and/or radiofrequency ablation.

Methods: Cross-sectional study analyzing 2,966 patients undergoing electrophysiological study and/or catheter ablation, from June 1997 to February 2013, in the Institute of Cardiology of Rio Grande do Sul. A total of 1490 procedures were performed in women, of whom 769 were of childbearing age. All patients were screened with a pregnancy test on the day before the procedure.

Results: Three patients tested positive, and were therefore unable to undergo the procedure. The prevalence observed was 3.9 cases per 1,000 women of childbearing age.

Conclusion: Because of their safety and low cost, pregnancy screening tests are indicated for all women of childbearing age undergoing radiological studies, since the degree of ionizing radiation needed for these procedures is very close to the threshold for teratogenicity, especially in the first trimester, when the signs of pregnancy are not evident. (Arq Bras Cardiol. 2013;101(5):418-422)

Keywords: Radiation, Ionizing; Women; Fertile Period; Risk Assessment; Catheter Ablation.

Introduction

An electrophysiological study (EPS) is an invasive procedure used for the diagnosis of disturbances in the rhythm and electrical conduction of the heart. It can be used to measure atrioventricular conduction intervals, to elucidate arrhythmogenic mechanisms, and to evaluate the efficacy of antiarrhythmic agents. It is currently also used to locate and map reentrant circuits and ectopic sources in detail, for further treatment with catheter ablation. Thus, it has a diagnostic, therapeutic, and prognostic purpose

Since the 1970’s, catheters have been positioned in cardiac chambers by means of fluoroscopy with X-ray emission. However, it is known that the exposure of a pregnant woman to this radiation can have consequences to the fetus, especially between the 8th and 15th weeks of gestation (Table 1). However, it is very difficult and inaccurate to quantify the fetal exposure to radiation, because of the dynamic characteristics of the test, the intermittent use of radiation, the different X-ray tube positions, device calibration, and fetal position. Due to this variability, it is not possible to determine the exact amount of exposure, which is estimated by anatomical-mathematical models and in experimental animals (Table 2).

Brazilian guidelines and those of the American Heart Association do not recommend the use of the beta-HCG test in the screening of women of childbearing age undergoing electrophysiological procedures.

In the present study, we evaluated the number of female patients referred for EPS and/or radiofrequency ablation who tested positive for a pre-procedural beta-HCG test.

Methods

Cross-sectional study analyzing information from patients undergoing EPS and/or radiofrequency catheter ablation in the Electrophysiology Laboratory of the Institute of Cardiology of Rio Grande do Sul, between June 1997 and February 2013. All women of childbearing age underwent the pregnancy test (serum beta-HCG) on the day before the procedure.
The study was approved by the Research Ethics Committee of the Institute of Cardiology of Rio Grande do Sul/University Foundation of Cardiology. The database and statistical calculations were carried out using the MedCalc® V.7.3 software program. Categorical variables were expressed as absolute numbers and percentages. Continuous variables were expressed as mean ± standard deviation.

Results
From an initial sample of 2,966 patients, 1,490 were females, of whom 769 were of childbearing age (10 to 50 years, according to the World Health Organization).

The mean age of the women undergoing a pregnancy screening test was 33.6 ± 11.3 years, and the mean time of fluoroscopy during ablation was 10.8 ± 9 minutes.

A total of 556 ablations and 213 electrophysiological studies were performed in women of childbearing age. The procedures had been indicated for the investigation of supraventricular tachycardia in most of the cases; 236 cases of nodal reentry tachycardia and 203 cases of atrioventricular reentry tachycardia were diagnosed.

Of the 769 women of childbearing age referred for catheter ablation, three had their procedures suspended because they tested positive for beta-HCG and were in the beginning of pregnancy, which was unknown to them until the test was performed. Thus, a prevalence of 3.9 cases per 1000 women of childbearing age referred for electrophysiological study was observed.

Since the cost of a beta-HCG test in the Single Health System is of approximately R$ 7.00, we can estimate that approximately R$ 1794.00 were necessary to prevent fetal radiation exposure during ablation procedures in their mothers.

Table 3 shows the procedures performed by the Laboratory of Electrophysiology of the Institute of Cardiology of Rio Grande do Sul.

Discussion
Exposure to ionizing radiation during diagnostic and therapeutic procedures has dramatically increased in the past years.

Fetuses are susceptible to teratogenic effects through the complete prenatal period, and are more vulnerable in the first trimester of pregnancy. These effects depend on several variables, including the gestational age, fetal mechanisms of cell repair, and level of absorption of the radiation dose.

There is no evidence that a radiation dose lower than 0.10 Gy is related to severe complications for the fetus. Specific effects, such as growth restriction, prenatal death, organ malformation, and intelligence impairment, are related to doses higher than 0.10-0.20 Gy. In the first weeks of gestation, the secondary effect of radiation may be the induction of abortion, which usually results from doses higher than 1 Gy. After 4 weeks, there may be the risk of organ malformation and overall growth retardation.
Deleterious effects on the central nervous system are more evident in exposures during the period between the 8th and 15th week of gestation, from the threshold dose of approximately 0.30 Gy.

In relation to the carcinogenic potential, this is present both in fetal exposure in the first trimester and in the other trimesters\(^{25,26}\). The risk of a fatal cancer is of approximately 5 to 15% per Gy\(^8\), and the risk of inherited genetic effects is of approximately 0.2 to 1% per Gy\(^{25}\). Calkins et al\(^{27}\) estimated that the risk of fatal malignancy is of 1 for every 1000 patients per hour of fluoroscopy.

However, resolution 453 of the National Agency of Sanitary Surveillance (Agência Nacional de Vigilância Sanitária – ANVISA) recommends that the dose on the abdominal surface does not exceed 2 mSv during all pregnancy, thus making it unlikely that the additional dose on the embryo or fetus exceeds approximately 1 mSv in this period\(^{28}\).

Currently, a growing interest and concern regarding protective measures and the least possible exposure to radioactive effects have been observed. It is believed that new technologies such as electroanatomical mapping and intracardiac three-dimensional echocardiography, which eliminate the use of radiation, could be used in these procedures and that they will be introduced gradually\(^2\).

In the present study, we observed that half of the women referred to our service were of childbearing age. Three cases of pregnancy were detected among 769 female patients of childbearing age. The estimated additional cost for this detection was of approximately R$ 5383.00. These preliminary data raise the discussion about the cost-effectiveness analysis of the measure. This information is important when we compare the risks attributed to the use of medications for the treatment of arrhythmias, such as amiodarone and verapamil, which are known to be potentially teratogenic. Additionally, the screening enables the prevention of radiation exposure and guidance on the decision-making about the drug therapy. Data in the literature on the cost-effectiveness of performing a beta-HCG test to prevent possible fetal malformations are unknown.

The teratogenic effect of radiation in the gestational period is well established, although few data are available in relation to exposure during EPS and/or catheter ablation.

Despite the ANVISA recommendations, the national guidelines still do not recommend the performance of beta-HCG test in the screening of female patients of childbearing age undergoing EPS and radiofrequency ablation\(^{6,7}\).

**Limitations**

The radiological exposure of each patient in different body positions was not assessed, since the dosimeter is positioned next to the procedure table. This information would permit a more precise quantification of the fetal exposure to radiation.

The real cost-effectiveness analysis was not carried out prospectively and thus only an approximate estimate is available. Additionally, the risks considered are those of maternal exposure to radiation and not of fetal malformation.

**Conclusion**

We demonstrated that the risk of exposure to ionizing radiation of women of childbearing age referred for radiofrequency ablation is significant. The amount of radiation necessary in these procedures is not negligible, especially in the first trimester, when the signs of pregnancy are not evident. The real cost-effectiveness analysis could not be carried out, but we propose that the pregnancy screening be incorporated to the national guidelines and to the routine of electrophysiology laboratories prior to the performance of elective procedures that require fluoroscopy.

**Author contributions**

Conception and design of the research and Critical revision of the manuscript for intellectual content: Lima GG, Gomes DG, Gensas CS, Simão MF, Rios MN, Kruse ML, Leiria TLL, Pires LM; Acquisition of data: Lima GG, Gomes DG, Gensas CS, Simão MF, Rios MN, Kruse ML, Pires LM; Analysis and interpretation of the data: Lima GG, Gomes DG, Gensas CS, Simão MF, Rios MN; Statistical analysis: Lima GG, Gomes DG, Leiria TLL; Writing of the manuscript: Lima GG, Gomes DG, Gensas CS, Simão MF, Rios MN, Leiria TLL, Pires LM.

**Potential Conflict of Interest**

No potential conflict of interest relevant to this article was reported.

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**Study Association**

This study is not associated with any post-graduation program.

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**Table 3 - Number of tests performed by gender**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Tests performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>1,476</td>
</tr>
<tr>
<td>Women</td>
<td>1,490</td>
</tr>
<tr>
<td>Women of childbearing age</td>
<td>769</td>
</tr>
<tr>
<td>Total</td>
<td>2,966</td>
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References


