

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

Gustavo Glotz de Lima, Daniel Garcia Gomes, Caroline Saltz Gensas, Mariana Fernandez Simão, Matheus N. Rios, Leonardo Martins Pires, Marcelo Lapa Kruse, Tiago Luiz Luz Leiria

Instituto de Cardiologia, Fundação Universitária de Cardiologia, Porto Alegre, RS - Brazil

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 purpose¹.

Since the 1970's, catheters have been positioned in cardiac chambers by means of fluoroscopy with X-ray emission². 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)³. 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 determinate the exact amount of exposure, which is estimated by anatomical-mathematical models and in experimental animals (Table 2)⁴.

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 procedures⁵⁻⁷.

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.

Mailing Address: Gustavo Glotz de Lima •

Avenida Princesa Isabel, 370, Santana. Postal Code 90620-000, Porto Alegre, RS – Brazil

E-mail: gglima.pesquisa@gmail.com

Manuscript received March 13, 2013; revised manuscript May 24, 2013; accepted June 03, 2013.

DOI: 10.5935/abc.20130192

Table 1 - Estimated radiation exposure during imaging tests, based on chest radiography multiples in the anteroposterior (AP) view

Test	Dose (mSv)	Chest radiography multiples (AP view)
Chest radiography AP	0.02	1
Chest radiography in AP and lateral	0.10	5
Invasive diagnostic coronary angiography	7	350
Percutaneous coronary intervention	15	750
Radiofrequency ablation	15	750

Modified Einstein¹⁵.

Table 2 - Estimated radiation dose in the fetus during ionizing radiation procedures⁸⁻¹³

Test	Estimate (mGy)	Range (mGy)	References
Catheter ablation (1st. trimester)	0.15	0.04-0.20	8,9
Catheter ablation (2nd. trimester)	0.3		9
Catheter ablation (3rd trimester)	0.6		9
Chest angiography for PTE (1st. trimester)	0.02	0.006-0.05	10
Aortic angiography	34		11
Abdominal CT scan (routine)	10	4-60	11, 12, 13
Cerebral angiography	0.06		8

PTE: pulmonary thromboembolism; CT: computed tomography.

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 \pm 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 fetus¹⁴. Specific effects, such as growth restriction, prenatal death, organ malformation, and intelligence impairment, are related to doses higher than 0.10-0.20 Gy¹⁵⁻²⁴.

In the first weeks of gestation, the secondary effect of radiation may be the induction of abortion^{8,16-18}, which usually results from doses higher than 1 Gy. After 4 weeks, there may be the risk of organ malformation and overall growth retardation.

Table 3 - Number of tests performed by gender

	Tests performed
Men	1,476
Women	1,490
Women of childbearing age	769
Total	2,966

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 Gy⁸, and the risk of inherited genetic effects is of approximately 0.2 to 1% per Gy²⁵. Calkins et al²⁷ 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 period²⁸.

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 gradually².

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.

Sources of Funding

There were no external funding sources for this study.

Study Association

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

References

1. Gensas CS, Pires LM, Kruse ML, Leiria TL, Gomes DG, Lima GG. Agnesia da veia cava inferior. *Rev Bras Cardiol Invasiva*. 2012;20(4):427-30.
2. Pires LM, Leiria TL, Mantovani A, Kruse ML, Ronsoni R, Gensas CS, et al. Initial experience of catheter ablation without the use of fluoroscopy. *Relampa*. 2012;25(4):267-72.
3. Shaw P, Duncan A, Vouyouka A, Ozsvath K. Radiation exposure and pregnancy. *J Vasc Surg*. 2011;53(1 Suppl):28S-34S.
4. Dauer LT, Thornton RH, Miller DL, Damilakis J, Dixon RG, Marx MV, et al; Society of Interventional Radiology Safety and Health Committee; Cardiovascular and Interventional Radiology Society of Europe Standards of Practice Committee. Radiation management for interventions using fluoroscopic or computed tomographic guidance during pregnancy: a joint guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe with Endorsement by the Canadian Interventional Radiology Association. *J Vasc Interv Radiol*. 2012;23(1):19-32.
5. Buxton AE, Calkins H, Callans DJ, DiMarco JP, Fisher JD, Greene HL, et al; American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (ACC/AHA/HRS Writing Committee to Develop Data Standards on Electrophysiology). ACC/AHA/HRS 2006 key data elements and definitions for electrophysiological studies and procedures: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (ACC/AHA/HRS Writing Committee to Develop Data Standards on Electrophysiology). *Circulation*. 2006;114(23):2534-70.
6. Sosa EA, de Paola A, Gizzi J, Rassi S, Scanavacca M, Pérez A, et al. Indicações para estudo eletrofisiológicos e ablação por cateter de arritmias cardíacas. Recomendações da DAEC da SBC. *Arq Bras Cardiol*. 1995;64(2):149-51.
7. Lorga A, Lorga Filho A, D'Ávila A, Rassi A Jr, Paola AV, Pedrosa A, et al; Sociedade Brasileira de Cardiologia. Diretrizes para avaliação e tratamento de pacientes com arritmias cardíacas. *Arq Bras Cardiol*. 2002;79(supl.5):1-50.
8. Stabin MG, Blackwell R, Brent RL, Donnelly E, King VA, Lovins K, et al. Fetal radiation dose calculations. ANSI N13.54-2008. Washington, DC: American National Standards Institute; 2008.
9. Damilakis J, Theocharopoulos N, Perisinakis K, Manios E, Dimitriou P, Vardas P, et al. Conceptus radiation dose and risk from cardiac catheter ablation procedures. *Circulation*. 2001;104(8):893-7.
10. Winer-Muram HT, Boone JM, Brown HL, Jennings SG, Mabie WC, Lombardo GT. Pulmonary embolism in pregnant patients: fetal radiation dose with helical CT. *Radiology*. 2002;224(2):487-92.
11. McCollough CH, Schueler BA, Atwell TD, Braun NN, Regner DM, Brown DL, et al. Radiation exposure and pregnancy: when should we be concerned? *Radiographics*. 2007;27(4):909-17.
12. Wagner LK, Lester RG, Saldana LR. Exposure of the pregnant patient to diagnostic radiations: a guide to medical management, 2nd ed. Madison, WI: Medical Physics Publishing; 1997.
13. Hurwitz LM, Yoshizumi T, Reiman RE, Goodman PC, Paulson EK, Frush DP, et al. Radiation dose to the fetus from body MDCT during early gestation. *AJR Am J Roentgenol*. 2006;186(3):871-6.
14. Zipes DP, Camm AJ, Borggrefe M, Buxton AE, Chaitman B, Fromer M, et al; American College of Cardiology/American Heart Association Task Force; European Society of Cardiology Committee for Practice Guidelines; European Heart Rhythm Association and the Heart Rhythm Society. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death--executive summary: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death) Developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. *Eur Heart J*. 2006;27(17):2099-140.
15. Einstein AJ. Effects of radiation exposure from cardiac imaging: how good are the data? *J Am Coll Cardiol*. 2012;59(6):553-65.
16. Jankowski CB. Radiation and pregnancy: putting the risks in proportion. *Am J Nurs*. 1986;86(3):260-5.
17. Einstein AJ, Moser KW, Thompson RC, Cerqueira MD, Henzlova MJ. Radiation dose to patients from cardiac diagnostic imaging. *Circulation*. 2007;116(11):1290-305.
18. De Santis M, Di Gianantonio E, Straface G, Cavaliere AF, Caruso A, Schiavon F, et al. Ionizing radiations in pregnancy and teratogenesis: a review of literature. *Reprod Toxicol*. 2005;20(3):323-9.
19. International Commission on Radiological Protection. Pregnancy and medical radiation. *Ann ICRP*. 2000;30(1):iii-viii,1-43.
20. Wieseler KM, Bhargava P, Kanal KM, Vaidya S, Stewart BK, Dighe MK. Imaging in pregnant patients: examination appropriateness. *Radiographics*. 2010;30(5):1215-29.
21. Streffer C, Shore R, Konermann G, Meadows A, Uma Devi P, Preston Withers J, et al. Biological effects after prenatal irradiation (embryo and fetus). A report of the International Commission on Radiological Protection. *Ann ICRP*. 2003;33(1-2):5-206.
22. American College of Radiology (ACR). Practice Guideline for imaging pregnant or potentially pregnant adolescents and women with ionizing radiation. Reston, VA; 2008.
23. Timins JK. Radiation during pregnancy. *N J Med*. 2001;98(6):29-33.
24. Miller RW. Discussion: severe mental retardation and cancer among atomic bomb survivors exposed in utero. *Teratology*. 1999;59(4):234-5.
25. Otake M, Schull WJ, Lee S. Threshold for radiation-related severe mental retardation in prenatally exposed A-bomb survivors: a re-analysis. *Int J Radiat Biol*. 1996;70(6):755-63.
26. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103. *Ann ICRP*. 2007;37(2-4):1-332.
27. Calkins H, Niklason L, Sousa J, el-Atassi R, Langberg J, Morady F. Radiation exposure during radiofrequency catheter ablation of accessory atrioventricular connections. *Circulation*. 1991;84(6):2376-82.
28. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Portaria SVS nº 453, de 1º de junho de 1998: aprova o regulamento técnico que estabelece as diretrizes básicas de proteção radiológica em radiodiagnóstico médico e odontológico, dispõe sobre o uso dos raios-x diagnósticos em todo território nacional e dá outras providências. *Diário Oficial da União*; Brasília; 2 de junho; 1998.