ESC Europace (2026) **28**, euag030
https://doi.org/10.1093/europace/euag030

CLINICAL RESEARCH

Fluoroscopy-minimization strategy for catheter ablation of Supraventricular Tachycardia by wOmen OPerators: the STOOP Multicentre Registry

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Received 20 January 2026; accepted after revision 8 February 2026; online publish-ahead-of-print 26 February 2026

Aims Occupational exposure to ionizing radiation in electrophysiology may significantly affect the careers of women of reproductive age. The aim of the STOOP registry was to quantify the estimated yearly occupational radiation exposure of female electrophysiologists of reproductive age performing consecutive radiofrequency catheter ablation (RFCA) for supraventricular tachycardia (SVT) adopting a fluoroscopy-minimization strategy.

Methods Twelve European centres participated. All procedures were performed with a fluoroscopy-minimization strategy, guided by 3D mapping systems and following the As Low As Reasonably Achievable (ALARA) principles.

Results A total of 710 RFCA procedures were performed by 32 operators (mean age38 ± 7 years). Mean procedure time was 80 ± 35 min, with a mean fluoroscopy time of 51 ± 153 s. The mean operator annual dose–area product (DAP) was 46.7 ± 79.5 Gy·cm², corresponding to an estimated mean annual effective dose of 9.34 ± 15.9 µSv. In no case did the yearly effective dose reach the 1 mSv occupational limit for pregnancy. The mean DAP did not differ among operators and was unaffected by operator experience or annual procedure volume.

Conclusion Performing SVT ablation with a fluoroscopy-minimization strategy results in operator radiation exposure far below the 1 mSv foetal dose constraint applicable once pregnancy is declared, irrespective of operator experience or case volume. These findings support the safety of continuing electrophysiology activity for women of reproductive age under modern fluoroscopy-free workflows.

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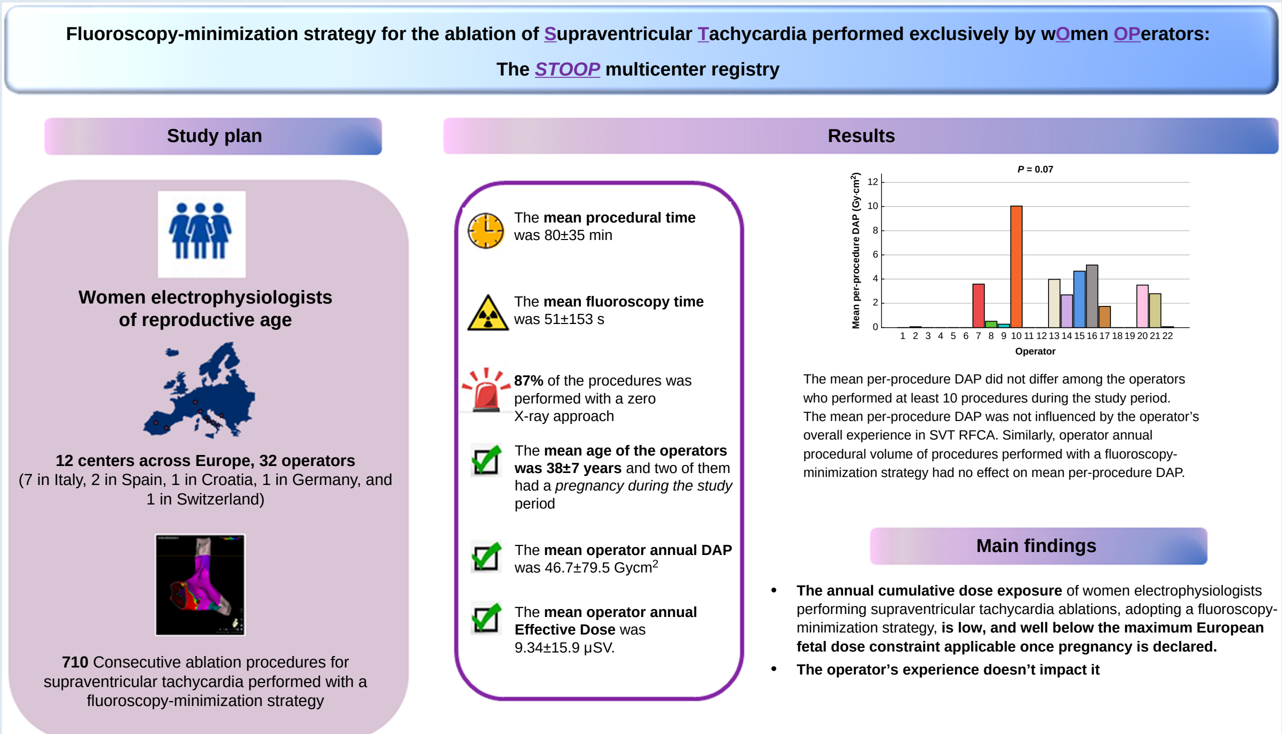
Graphical Abstract



Keywords DAP • Zero fluoroscopy • Effective dose • Catheter ablation • Supraventricular tachycardia

What's new?

- The STOOP registry quantified the estimated yearly occupational radiation exposure of female electrophysiologists of reproductive age performing consecutive radiofrequency catheter ablation (RFCA) for supraventricular tachycardia (SVT) adopting a fluoroscopy-minimization strategy.
- A total of 710 RFCA procedures were performed by 32 operators (mean age38 ± 7 years). Mean procedure time was 80 ± 35 min, with a mean fluoroscopy time of 51 ± 153 s.
- The mean operator annual dose–area product (DAP) was 46.7 ± 79.5 Gy·cm², corresponding to an estimated mean annual effective dose of 9.34 ± 15.9 µSv. In no case did the yearly effective dose reach the 1 mSv occupational limit for pregnancy. The mean DAP did not differ among operators and was unaffected by operator experience or annual procedure volume.
- Performing SVT ablation with a fluoroscopy-minimization strategy results in operator radiation exposure far below the 1 mSv foetal dose constraint applicable once pregnancy is declared, irrespective of operator experience or case volume.

Introduction

Radiofrequency catheter ablation (RFCA) is the cornerstone of therapy for supraventricular tachycardia (SVT), with a high success rate.[1] Conventional ablation requires fluoroscopy for catheter navigation, exposing both patients and operators to ionizing radiation. In Europe, the Council Directive 2013/59/Euratom[2] stipulates the basic safety standards for protection against the hazards of ionizing radiation. It sets an annual occupational exposure limit of 20 mSv, with stricter requirements for working women during pregnancy and breastfeeding. In this category, the directive limits foetal radiation exposure to <1 mSv. The heterogeneous application of these directives across Europe has, in some countries, resulted in restrictions on pregnant women working in electrophysiology (EP) laboratories, creating a radiological barrier that perpetuates the gender gap. Several studies have demonstrated that SVT RFCA procedures performed with a zero- or near-zero fluoroscopy approach are safe and as effective as conventional fluoroscopy-guided procedures.[3–7] The STOOP registry aimed to quantify the estimated yearly occupational radiation exposure of female electrophysiologists of reproductive age performing consecutive RFCA for SVT using a fluoroscopy-minimization strategy in accordance with As Low As Reasonably Achievable (ALARA) principles.

Methods

Study population

This prospective multicentre registry collected consecutive RFCA procedures for SVT performed by female electrophysiologists of reproductive age across participating centres. Following a preliminary survey on the adoption of the fluoroscopy-minimization strategy and adherence to ALARA principles, 12 centres across Europe (7 in Italy, 2 in Spain, 1 in Croatia, 1 in Germany, and 1 in Switzerland) participated in the study. The study protocol conformed to the ethical guidelines of the Declaration of Helsinki and was approved by the Institutional Ethics Committees. Each patient provided informed consent to participate in the study. Patients aged 14 years or older at the time of enrolment were eligible for inclusion. Exclusion criteria were patient pregnancy, contraindications to ionizing radiation exposure, life expectancy of <1 year, atrial fibrillation, ventricular tachycardia, presence of a congenital heart disease, and known abnormal venous access to the heart. All the operators were female of reproductive age performing consecutive RFCA for SVT.

Ablation procedures

All consecutive RFCA procedures performed in each centre according to current indications and clinical practice were included. No deviation from the usual workflow of each EP laboratory was required. All the available types of 3D mapping systems (CARTO, EnSite, Rhythmia, Affera, Columbus) were included, according to operator preference. All procedures were performed with a fluoroscopy-minimization strategy aiming at zero (completion of the entire procedure without the use of fluoroscopy) or near-zero (< 60 s) fluoroscopy, in accordance with the ALARA principles. Minimal fluoroscopy use was allowed if deemed necessary for procedural safety or efficacy. After obtaining the vascular accesses, a mapping or ablation catheter was inserted to reconstruct the vessel and heart chamber anatomy. Once the geometry was established, the remaining catheters were positioned using it as a guide for navigation and placement. Modern mapping systems provide real-time localization of catheter electrodes, allowing accurate three-dimensional reconstruction of the cardiac and vascular anatomy and continuous visualization of the entire catheter within the heart, simplifying navigation, and speeding up subsequent phases of the procedure. Whenever transseptal access was required, it was guided by intracardiac or transoesophageal echography or fluoroscopy depending on centre availability and operator preference.

In patients with atrioventricular nodal re-entrant tachycardia (AVNRT), RF was delivered on slow pathway potential with an AV ratio < 1:2. The endpoint of the ablation was to obtain junctional beats during RF application and the non-inducibility of the AVNRT. In patients with atrioventricular re-entrant tachycardia (AVRT), RF was delivered on the shortest AV or VA potential aiming at the abolition of both anterograde and retrograde accessory pathway conduction. In patients with atrial flutter (AFL), a linear lesion was delivered along the critical isthmus to achieve interruption of the AFL and bidirectional block along the isthmus. In patients with atrial tachycardia (AT), RF was delivered at the site of earliest atrial activation aiming at AT interruption and no longer induction. In all patients a waiting time of 20 min was observed, and post-ablation electrophysiological study was performed in the basal state and during isoproterenol infusion.

We collected data on complications that occurred acutely and within 30 days after the index procedure.

Radiation exposure

Radiation exposure for each procedure was measured using the dose–area product (DAP), which, unlike the dosimeter, is readily available from all imaging system vendors and allows to exclude from the measurement the amount of fluoroscopy needed for implantable cardiac devices or complex arrhythmia ablation (atrial fibrillation, ventricular tachycardia) a standardized parameter automatically provided by all fluoroscopy systems and linearly correlating with true estimated effective biological dose.[8,9] In EP procedures, the operator's effective dose can be estimated indirectly from the patient's DAP using empirical conversion coefficients and correction factors:

$$E\text{op} \approx k\text{EP} \times \text{DAP} \times f\,\text{dist} \times f\,\text{shield} \times f\,\text{ang}$$

where *E*op = operator effective dose (μSv); DAP = patient DAP (Gy·cm²); *k*EP = empirical conversion coefficient specific for EP procedures; *f*dist = correction factor for operator–patient distance; *f*shield = correction factor for shielding (lead apron, ceiling-suspended screen, under-table drape); and *f*ang = correction factor for X-ray beam angulation.

For modern EP laboratories using shielding and without cineangiography, *k*EP ≈ 0.1–0.2 μSv/(Gy·cm²).[8,9] For this study we used a *k*EP = 0.2 μSv/(Gy·cm²) assuming a 1 m operator–patient distance, adequate shielding, and standard beam angulation. We also performed a dedicated sensitivity analysis, modifying distance- and projection-related correction factors, to assess the robustness of the operator effective dose estimates with respect to key model assumptions. In particular, for *f*dist, 100 cm = 1, 50 cm = 4, 25 cm = 16, and for *f*ang, standard angulation (AP and mild RAO) = 1, RAO = 1.5, steep LAO ± cranial/caudal = 3.

Across participating centres, fluoroscopy, when used, was performed with low frame rates (typically 3.15–7.5 fps). Systematic collimation was usually applied in all cases, restricting the X-ray field to the minimal area necessary for catheter visualization. Dose-saving algorithms were enabled. In all centres, limited projections (postero-anterior, antero-posterior, left anterior oblique 30°, and right anterior oblique 30°) were used, avoiding steep angulations whenever possible. With respect to radiation protection, all centres routinely employed ceiling-suspended lead screens and table-mounted lead drapes, with personal protective equipment providing a lead equivalence of at least 0.5 mm Pb.

Endpoints

For this analysis, only operators who performed SVT RFCA for at least 1 year were included, so that each operator contributed cases over 12 consecutive months. The primary endpoint was the estimated annual radiation exposure, derived from the DAP, for female electrophysiologists of reproductive age performing consecutive RFCA for SVT. Secondary endpoints were the reproducibility of the fluoroscopy-minimization strategy and the influence of operator experience on its implementation. To rank the operators according to their expertise, we divided them into lifetime SVT RFCA procedure (<100, 100–500, >500) and annual SVT RFCA procedure with zero or near-zero approach (<50, ≥50), as self-reported by each operator in the preliminary survey.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation or median and interquartile range according to data distribution. Normality was tested using the Shapiro–Wilk test. Categorical variables are reported as counts and percentages. Comparison among groups for continuous variables was performed using the unpaired Student's *t*-test or the Mann–Whitney *U* test. Categorical variables were compared using the χ^2 test. Since electrophysiological procedures were nested within operators and centres, to further establish the clinical significance of our findings, we applied mixed-effects linear regression models, a set of powerful statistical tools that extend standard linear regression to data with a multilevel hierarchical structure. These models included random intercepts for both operator and centre and were used to evaluate the associations between DAP and the main covariates considered in our study. One-way analysis of variance (ANOVA) was used to test all categorical covariates with more than two levels. Finally, clinically relevant interactions were examined in all models, with particular attention to the potential associations between DAP, sex, and body mass index. Statistical analyses were performed using SPSS software (Version 24.0; IBM, Armonk, NY).

Results

Patients

A total of 710 SVT RFCA procedures were included. The mean age was 54 ± 19 years; 388 (55%) were male, and 322 (45%) female. The mean height and weight were170 ± 10 cm and 75 ± 17 kg, respectively.

Operators

Ablation procedures were performed by 32 operators. The mean operator age was 38 ± 7 years, and two operators were

Table 1 Operator-level per-procedure and annual radiation exposure of operators who performed at least 10 procedures during the study period

Operator	Procedures	Mean per-procedural DAP (Gy·cm²)	Median per-procedural DAP (Gy·cm²)	Minimum-Maximum per-procedural DAP (Gy·cm²)	Annual cumulative DAP (Gy·cm²)	Derived annual effective dose (µSv)
1	40	0 ± 0	0 (0–0)	0–0	0	0
2	14	01 ± 2.1	0 (0–0)	0–0.79	0.8	0.16
3	11	0 ± 0	0 (0–0)	0–0	0	0
4	11	0 ± 0	0 (0–0)	0–0	0	0
5	30	0 ± 0	0 (0–0)	0–0	0	0
6	31	0 ± 0	0 (0–0)	0–0	0	0
8	21	3.6 ± 10	0 (0–0.75)	0–41	74.9	14.98
9	71	0.5 ± 1.5	0 (0–0)	0–10	34.7	6.94
15	32	0.2 ± 1.3	0 (0–0)	0–7.48	7.6	1.52
18	20	10 ± 44	0 (0–0)	0–195.9	200.8	40.18
19	39	0 ± 0.2	0 (0–0)	0–0.12	0.2	0.04
20	40	0 ± 0.2	0 (0–0)	0–0.1	0.1	0.02
21	48	4 ± 3.5	3.2 (1.2–5.8)	0–15.9	190.9	38.18
22	18	2.7 ± 2	1.7 (1.3–4.3)	0.96–8.28	43	8.6
23	16	4.7 ± 8.8	0.9 (0–4.9)	0–28.5	74.6	14.92
24	14	5.2 ± 8.5	2.2 (0.7–6.1)	0–32.1	282.8	53.56
25	86	1.7 ± 15	0 (0–0)	0–133	135	27
26	15	0 ± 0	0 (0–0)	0–0	0	0
28	11	0 ± 0	0 (0–0)	0–0	0	0
29	41	3.5 ± 8.2	0 (0–3.1)	0–37.8	126	25.2
31	13	2.8 ± 5.2	0 (0–7.5)	0–12.3	22.3	4.46
32	41	0.1 ± 0.4	0 (0–0)	0–2.37	2.4	0.48

pregnant during the study period. Most (59%) reported performing <50 fluoroscopy-minimization strategy procedures per year. Regarding lifetime experience with SVT RFCA, 28% had performed <100 procedures, 34% between 100 and 500, and 38% >500.

Procedural data and acute success

Of the 710 procedures included, 594 (84%) were performed in patients with documented SVT, while the remaining cases involved patients with symptoms suggestive of SVT or ventricular pre-excitation. The mapping systems used were CARTO in 331 procedures, EnSite in 326, Rhythmia in 49, Affera in 4, and a Columbus in 1 patient.

Following electrophysiological evaluation, AVNRT was diagnosed in 360 patients (51%), AFL in 201 (28%), AVRT in 101 (14%), and AT in 43 (6%). In five patients, no SVT was inducible. However, based on prior documentation of SVT and evidence of dual AV nodal physiology during the EP study, slow pathway ablation was performed.

The mean procedure time was 80 ± 35 min, with a mean fluoroscopy time of 51 ± 153 s; 62 (8.7%) procedures required transseptal puncture, and, among these, 23 were performed under intracardiac or transoesophageal echocardiography and 39 under fluoroscopic guidance. Overall 555/710 (78%) procedures were performed without fluoroscopy, 33/710 (5%) with a near-zero approach, and 122/710 (17%) with a fluoroscopy time > 60 s. Acute success was reported in 693/710 (98%) patients, with only two complications: one vascular haematoma and one atrioventricular block.

Radiation exposure (DAP and effective dose)

Table 1 summarizes operator-level per-procedure and annual radiation exposure of operators who performed at least 10 procedures during the study period. The mean operator annual DAP was 46.7 ± 79.5 Gy·cm², corresponding to a mean annual operator effective dose of 9.34 ± 15.9 µSv. In the worst-case assumption ($f$dist, 16; $f$ang, 3), the mean annual operator effective dose is 448.32 ± 763.2 µSv. The yearly effective dose remained below the regulatory limit of 1 mSv for all operators. The mean per-procedure DAP did not differ among the several operators who performed at least 10 procedures during the study period (*Figure 1*). The mean per-procedure DAP was not influenced by the operator's overall experience in SVT RFCA (0.76 ± 2.5 Gy·cm² for operators with fewer than 100 procedures, 2 ± 14.1 Gy·cm² for 100–500 procedures, and 1.6 ± 11.8 Gy·cm² for >500, $P = 0.66$; *Figure 2*). Similarly, operator annual procedural volume of procedures performed with a fluoroscopy-minimization strategy had no effect on mean per-procedure DAP (1.77 ± 4.5 Gy·cm² for operators performing fewer than 50 procedures per year vs. 1.52 ± 14.9 Gy·cm² for those

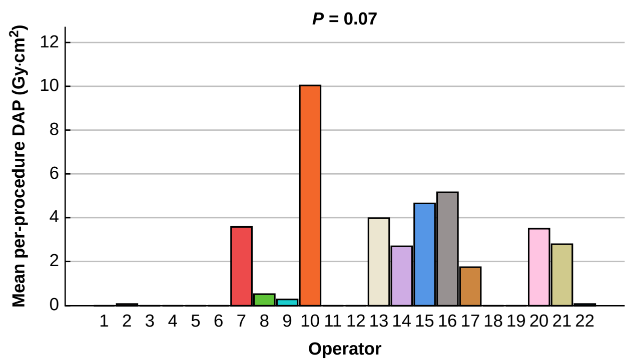


Figure 1 The mean per-procedure DAP among operators who performed at least 10 procedures during the study period.

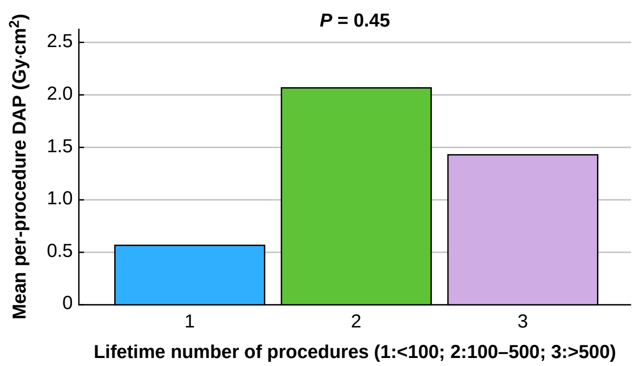


Figure 2 The mean per-procedure DAP according to the overall operator's experience in performing SVT RFCA.

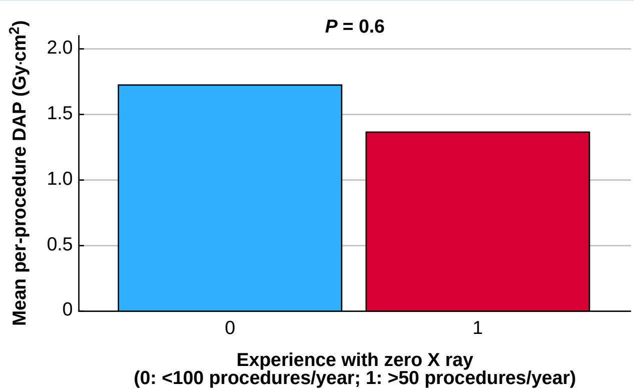


Figure 3 The mean per-procedure DAP according to the operator's volume of yearly procedures performed with a fluoroscopy-minimization strategy.

performing >50, $P = 0.95$; *Figure 3*). The type of SVT did not affect the mean per-procedure DAP (*Figure 4*), although slightly higher values were observed in atrioventricular re-entrant and atrial tachycardias, likely reflecting the use of fluoroscopy-guided transseptal puncture in selected cases. Indeed, the mean DAP was slightly higher in procedures requiring transseptal punctures (2.7 ± 4.9 Gy·cm^2 vs. 1.7 ± 13.3 Gy·cm^2, $P = 0.58$).

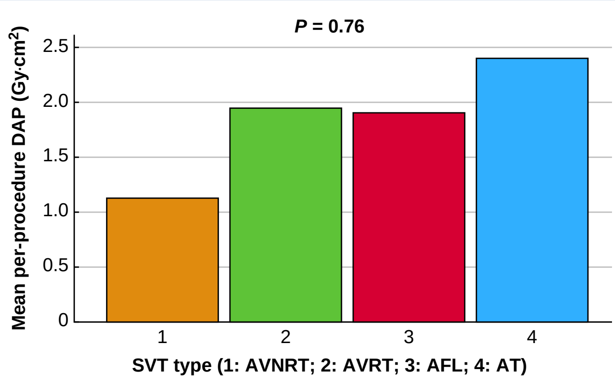


Figure 4 The mean per-procedure DAP according to the type of SVT.

The mixed-effect linear regression models to assess the association between the DAP and the different covariates showed a significant association only with the mapping system. Compared with CARTO procedures, the DAP was significantly higher with the Rhythmia system (beta = 5.1; CI 95%, 1.7–8.4; $P = 0.014$) (see Supplementary material). Finally, within our mixed-effects linear regression models, we tested for interactions with sex and BMI. All the interaction *P*-values were >0.2, indicating no statistically significant interactions.

Discussion

The STOOP Multicentre Registry demonstrated that the annual radiation exposure of female electrophysiologists of reproductive age performing consecutive SVT ablations with a fluoroscopy-minimization strategy approach remained well below the European occupational limit of 1 mSv. This finding was consistent across operators, regardless of overall experience or annual procedural volume.

Catheter insertion and manipulation in EP have traditionally relied on fluoroscopy, resulting in occupational exposure for both operators and trainees. In Europe, the Council Directive 2013/59/Euratom, taking into account the recommendations from the International Commission on Radiological Protection,[9] establishes basic safety standards for protection against ionizing radiation, setting an annual occupational limit of 20 mSv and a foetal dose not exceeding 1 mSv once pregnancy is declared. Although pregnancy does not require discontinuation of professional activity, employers must ensure compliance with these limits and implement appropriate monitoring and protective measures.

Concerns about occupational radiation exposure before and during pregnancy are among the reasons for the persistent underrepresentation of women in EP.[10] Although several protective strategies are available, including equipment-based and personal measures, as well as the use of three-dimensional electroanatomical mapping systems that allow near-zero exposure once the mapping or ablation has begun, their adoption remains inconsistent during EP procedures.[11,12] Several studies have demonstrated that zero- or near-zero fluoroscopy procedures are safe and as effective as those performed using conventional fluoroscopy-guided approaches.[3–7] Adeliño *et al.*[10] investigated the occupational radiation exposure and the related concerns among operators, particularly women. In that survey, zero- or near-zero fluoroscopy techniques were the preferred strategy during pregnancy, yet >35% of female responders reported never having performed a zero- fluoroscopy approach.

In the Charisma Registry,[13] female gender was inversely related to fluoroscopy use, possibly reflecting greater attention to radiation risks, particularly among younger, reproductive-age physicians. Similarly, Kosiuk *et al.*[14] reported data from 14 European countries on 1788 cases (9% diagnostic procedures, 38% atrial fibrillation ablations, 44 SVT ablations, and 9% ventricular ablations) in a multicentre European registry. In the multivariate analysis, only female gender (OR 1.707, 95% CI 1.257–2.318, $P = 0.001$) characterized operators conducting lower exposure procedures. This is in line with the fact that the use of fluoroscopy is perceived as a major concern by young electrophysiologists of reproductive age. Indeed, most (67%) respondents in the EHRA survey[10] claimed to be worried about the effects of occupational radiation exposure on reproductive capacity.

To date, no data have been available on the annual effective dose received by operators performing all SVT RFCA procedures. The STOOP Multicentre Registry is the first collaborative study to test whether using a fluoroscopy-minimization strategy results in an annual operator exposure below the European occupational limit of 1 mSv, which also defines the current threshold for foetal dose constraint applicable once pregnancy is declared. Although EHRA[11,12] recommends the use of 3D mapping systems to minimize exposure once the mapping or ablation process has started, it emphasizes that the extent of reduction depends on operator experience and system accuracy. In the STOOP registry, DAP was not influenced by arrhythmia type, overall operator experience in SVT RFCA, or operator annual fluoroscopy-minimization strategy procedure volume. These results are consistent with the findings reported by Lehar *et al.*[15] who reported that operators rapidly adapted after adopting a zero fluoroscopy approach. Moreover, all the currently available 3D mapping systems were represented in the registry, and no significant differences in DAP were observed among operators. Importantly, none of the 32 operators, all fertile women, performing consecutive RFCA for SVT reached the European occupational limit of 1 mSv foetal dose constraint applicable once pregnancy is declared, thus supporting the safety of continued professional activity during pregnancy. We hope that our findings will help women become more aware of their real radiological exposure risk and allow them, once informed, to continue working based on their own decision. These results provide objective evidence that may help clarify misconceptions about occupational radiation risk and allow women to continue working based on their own decision, potentially reducing the perceived radiological barrier contributing to the gender gap in interventional EP.[12]

If confirmed in larger series, these findings could support regulatory authorities to overcome the substantial discrepancies in how the Euratom Directive is applied among European countries. While some countries apply it literally, allowing women to work during pregnancy and breastfeeding, others impose stricter restrictions that prevent women from working in the EP Labs throughout this period perpetuating gender inequities in the field.

Limitations

Firstly, this was a non-randomized registry. No deviation from the clinical practice of each centre and operator was required. Such registries provide valuable insight into how ablation procedures are being performed in the ‘real world’ compared with controlled clinical trials that are often performed on a highly selected patient population in very experienced centres. Secondly, we collected data only on SVT RFCA. SVT RFCA represents only a portion of the operators' overall case mix. Data on radiation exposure from AF ablation, VT ablation, or device implantation were not collected and are acknowledged as beyond the scope of this registry. Thirdly, more complex arrhythmias often require a transseptal puncture. Although its optimization using three-dimensional mapping and unipolar electrogram monitoring at the needle tip has been reported[16] to reduce fluoroscopy exposure, in our registry the mean DAP was slightly higher in procedures requiring transseptal puncture. Further registries are warranted to assess the effective dose absorbed when performing more complex arrhythmias or device implantation or using different energy sources such as cryo or pulsed field energy.[17,18] Fourthly, to better quantify the impact of fluoroscopy-minimization strategy on occupational exposure, one could compare the radiation exposure from these SVT procedures to other SVT cases performed with a standard approach. However, the aim of the study was not comparative effectiveness, but objective quantification of cumulative exposure under a fluoroscopy-minimization strategy. Fifthly, the DAP is a patient dose proxy, and the operator dose is strongly influenced by beam geometry, scatter conditions, shielding configuration, and operator position. Accordingly, the operator effective dose reported in this study is model-derived rather than directly measured and should be interpreted as an indicative estimate for comparative and sensitivity analyses. Although the operator effective dose estimates varied by more than an order of magnitude under worst-case assumptions, the relative trends and conclusions of the study were unaffected. Finally, although all available 3D mapping systems were used, most of the data were collected using CARTO and EnSite systems. The small number of procedures performed with the Rhythmia system might also justify the higher mean per-procedure DAP observed with the Rhythmia system.

Conclusions

Performing SVT RFCA with a fluoroscopy-minimization strategy is safe and effective. Even when performed consecutively over an entire year, zero/near-zero fluoroscopy SVT RFCA contributes negligibly to annual occupational exposure relative to regulatory thresholds.

Supplementary material

Supplementary material is available at *Europace* online.

Patient consent statement

All the participants provided informed consent.

Funding

None.

Conflict of interest: none declared.

Ethics approval statement

This study was conducted in accordance with the Declaration of Helsinki Ethical the Good Clinical Practice, the corresponding national laws, the contemporaneous guidelines, and according to the current state of science and technology. Approval was granted by the Institutional Review Board.

Data availability

The data of this article will be shared on reasonable request to the corresponding author.

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