

Special Article: Radiofrequency Ablation

Fast Increase of Luminal Esophageal Temperature During High Power Short Duration Radiofrequency Ablation

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Introduction

PVI procedures by means of RF power local delivery is a widespread technique for the cure of AF. In the traditional procedure, point-by-point ablation is normally performed by successive applications of 20W power (or slightly more) for up to 60 s. It is well known that the heat so delivered may produce collateral damages, among which Esophageal Thermal Lesions (ETLs) are particularly feared, since in some cases esophageal ulcers may develop, within days or weeks, into devastating Atrio-Esophageal Fistula AEF, a rare complication but with a large mortality rate and heavy consequences for the survivors. HPSD-RFA is used more and more frequently, since it offers the advantage of shortening the procedure time and seems more effective in preventing AF recurrence [1]. Powers of 40-60 W are employed for durations of the order of 5-10 s (also larger powers can be used with shorter application times). HPSD-RFA proved to be as effective as the traditional procedure, as recognized by various meta-analyses, which however emphasize that complication rates, including ETLs, are similar to those occurring in the traditional procedure [2] (referring to 3867 patients). The strong reduction of the application time may induce electrophysiologists to believe that the new procedure has negligible influence on the patient LET, an aspect deserving attention for the patient safety. However, since large RF power is involved, it must be kept in mind that safety margins are reduced, as clearly stated in R.J. Knotts, C.R. Barbhaya, [3]. A tendency has emerged in distinguishing between resistive heat (the one producing the desired localized lesions) and conductive heat (the one diffusing from the ablation site). After all, heat is just

Abstract

Background: High Power Short Duration Radiofrequency Ablation (HPSD-RFA) is a technique more and more frequently used for Pulmonary Veins Isolation (PVI) for the cure of Atrial Fibrillation (AF). Owing to the short power release time, its impact on Luminal Esophageal Temperature (LET) may not be clear, inducing to underestimate the necessity of LET monitoring.

Methods: The issue above is examined, based on the relevant literature in the years 2020-2023.

Results: LET can attain dangerous level during HPSD-RFA with various possible complications.

Conclusions: During HPSD-RFA it is necessary to monitor the patient's LET using fast responding thermal sensors.

Abbreviations: AF: Atrial Fibrillation; AEF: Atrio-Esophageal Fistula; ETL: Esophageal Thermal Lesion; HPSD: High Power Short Duration; LET: Luminal Esophageal Temperature; RF: Radiofrequency; RFA: Radiofrequency Ablation; PVI: Pulmonary Veins Isolation

heat and once introduced in the system in any form, it starts travelling in all directions according to Fourier's law. Actually, this basic concept is not ignored in the literature. Indeed, in the review paper N. Szegedi, L. Gellér [4], after defining the two species of heat the authors warn that "one has to keep in mind that applying high power for a longer duration can cause extensive tissue injury damaging peri-cardiac structures such as the lungs or the esophagus".

In the present paper, we investigate the recent relevant literature about the effects that HPSD-RFA may have on patients LET during PVI procedures. Before passing to this specific subject, let us recall specific research pointing out that HPSD-RFA presents a markedly higher risk of stroke (see e.g. J. Merlino [5], recommending that such large powers have to be managed with great care).

A Short Overview of The Recent Literature Concerning LET Evolution During HPSD-RFA

The general principle underlying the question of LET increase is that once thermal energy is introduced in the body, while local effects (i.e. shape and depth of the desired lesions) depend on power, contact force, and duration, conduction takes heat well beyond the ablation site. Hence, the esophagus (and other organs as well) will inevitably be affected in a way that depends on the amount of energy delivered and, on the patient's, anatomical configuration. The total energy delivered is actually smaller in HPSD procedures than in the low power ablation, but

concerning LET increase, cases which are critical in the traditional RFA, because of the esophagus proximity to the ablation sites, still offer the risk of thermal lesions to the esophagus.

Let us report some papers in the years 2020-2023 that have considered the issue of LET evolution during HPSD-RFA trying to evaluate the risk of ETL occurrence. Clinical papers here included were limited to human applications only.

Clinical Papers

T. Kaneshiro et al. [6].

The aim of the paper was to compare the onset of complications in the traditional and in the HPSD procedures by examining two groups of patients who received the old or the new treatment (n=170 and n=101, respectively). Let us focus on the results concerning collateral thermal lesions: in the first group there were 38 ETLs (22%) vs. 37 (37%) in the second group. When assessing these results one should consider an important detail: LET was monitored in all the patients of the second group (using the Japanese 5-sensor Esophaster probe), but only in about one third of the first group. Failure to monitoring LET may increase the risk of producing ETLs, so one could expect that the 22% ETLs percentage in the first group could have been even lower if all the patients had received esophageal thermal monitoring, though it is not possible to quantify this statement. Even more striking is the information concerning gastric hypomotility, caused by vagal nerve injury: 28 cases (16%) in the first group vs. 33 (33%) in the second. Nevertheless, a more substantial difference consists in the severity of esophageal lesions: none was serious in the HPSD group, while ulcerations occurred in the traditional group (numbers not disclosed). Based on this, the authors conjectured that the heat delivered during HPSD procedure is less likely to reach the esophageal mucosa. Another nontrivial detail within the same framework is the alarm LET threshold that was used during monitoring, which was 41°C, which is rather high, considering that temperature keeps raising for a while after power switch off by 1°C or more in critical cases. Unfortunately, LET values are not provided, so it is not possible to draw a clear conclusion. An interesting information reported is the average total amount of RF energy along the left-sided posterior isolation line, distinguished for the upper area (5364 J traditional, 4363 J HPSD) and for the lower area (4604 J, 4209 J, resp.).

One more remark is in order. While esophageal ulcers (if not pre-existing) are clearly of thermal origin, small irritation like erythemas may not necessarily related to the action of heat only, but they might be induced by the simple contact of the metal of the probe sensors with the esophageal mucosa. In the past such a circumstance was erroneously associated to the so-called antenna effect (RF power capture by the metal sensors). Precisely the residual LET increase after power switch off proves that heat flows by conduction to the sensors from the surrounding tissue and not vice versa. The absence of serious esophageal lesions in the HPSD group led the authors to conclude that HPSD is more likely to spare the esophagus. Though such a conclusion looks coherent to the clinical results, the surprising large number of periesophageal nerves damage that occurred during HPSD procedures shows that heat is actually conducted from the ablator towards the esophagus, a fact that once more drives attention to LET monitoring. Indeed, the temperature difference between the inner and outer esophagus surfaces can be considerably large, as it was shown in the theoretical paper A. Fasano et al, [7], when the esophagus-ablator distance is relatively small.

Thus, keeping this into account, monitoring LET time behavior can provide some clue concerning the risk of possible injuries to vagal or phrenic nerves.

C.R. Barbhaiya et al. [8]

LET was monitored in 16 patients undergoing HPSD-RFA. The S-Cath CIRCA esophageal thermal probe was used. LET increments exceeding 2°C over baseline temperature were considered clinically significant. The median maximum LET (LET_{max}) increase observed at any point during the procedure was 3.5°C, with a peak of 5.8°C after a 50W, 6s application. LET increase was rightly correlated to the esophagus-ablator distance. In 8 cases the increase was larger than 4°C and 34 times was in the interval 2-4°C. No significant ETL was detected, but the fact remains that LET may increase considerably. This is important if one considers that patients may react very differently to LET variations. In the Discussion Section the authors state that "Significant esophageal heating related to an HPSD RF application seems to be confined to a region with a radius of about 2 cm and largely resolves within 60 seconds". It must be stressed that the left atrium-esophagus distance is very often less than 2 cm.

S. Chen et al. [9]

In this investigation 122 patients received HPSD-RFA (50W, avg. application time 7 s) with LET monitoring performed by means of the S-Cath CIRCA probe and an alarm temperature set at 39°C. Esophageal endoscopy was performed 1 to 3 days after the procedure. Threshold LET value was exceeded in 47% of cases. A LET peak of 45°C was reached in one case. Only 2 mild ETLs were found. Under the point of view of LET variations the most interesting information from this paper is that HPSD-RFA is actually able to raise LET to really alarming values.

J.-Y. Wielandts et al [10]

Two groups of 48 patients each were ablated with different power settings: 45 W (n=50, high power group) versus 35 W (n=50, control group). Alarm LET was set to 38.5°C. Endoscopy was performed in those patients who experienced a LET increase beyond threshold. This happened in 52% of cases in the control group and 40% of cases in the HPSD group (LET values not reported, nor the temperature recording system). One ETL occurred in each group: both were ulcerations, but the one in the HPSD group was accompanied by perforation. The authors conclude that "Temperature feedback in high power is at least as important as in low power".

H.D. Yavin et al. [11]

The aim of this paper was to compare HPSD-RFA with procedures employing powers and durations of moderate but not low level (e.g. 30W, 25 s). The two kinds of applications were carried out alternatively on the same patient and LET was monitored using the S-Cath CIRCA probe. Very similar LET increases were observed (peak of 39.3°C for HPSD and 39.4°C for the moderate power) and even the time evolution was similar: the LET vs. time curves (averaged over the patients) for the two application types are overlapping. Thus, this paper shows that heat propagation does not depend much (or not at all) on the applied power, but rather on the amount of released energy.

P. Halbfass et al. [12]

In two different centers (Bad Neustadt, Germany and Bruges, Belgium) 45+45 patients had very HPSD-RFA, i.e. with 90W, 4s point-by-point applications. In the Bruges center LET monitoring

(SensiTherm probe, St. Jude Medical) was used to allow cooling between successive applications. No ETLs were detected, though the authors warn that some ETL could have gone undetected because of the large time elapsed in some cases before endoscopy. Very interesting is the opinion expressed by the authors about the risks concerning collateral thermal damages during HPSD-RFA: "although HPSD ablation is generally associated with more shallow lesions, it is plausible that the larger area of resistive heating associated with vHPSD serves as a capacitor for a longer conductive heating phase". Of course, this strongly emphasizes the importance of keeping the thermal field under control.

D. Grosse Meininghaus et al. [13]

The paper reports a case of a patient who underwent HPSD-RFA (50W for max 13s) and got an esophageal perforation, not developed into AEF. LET was monitored with the S-Cath CIRCA probe with an alarm temperature of 41°C. The maximal LET reached after power switch off was 42°C. This case proves that great care must be used when using high power and that LET monitoring is crucial.

J. Wörmann et al. [14]

Here HPSD-RFA was compared with cryo-ablation in two groups with 46 and 675 patients, respectively. In short, the conclusion was that the two procedures are equally effective, but we are interested in the fact that this study included LET monitoring (S-Cath CIRCA probe, alarm temperature 40°C). In HPSD-RFA power was set at 70W, duration between 5s and 7s, and no major complication was reported. The paper does not include LET data, but still it supports the expectation that substantial LET increase can occur.

C.H. Heeger [15]

In this trial 50+50 patients were treated with very HPSD-RFA (90W, 4s) and with the conventional RFA (max 40W), respectively. The S-Cath CIRCA probe was used for LET monitoring (alarm threshold 38.5°C) in the first group only. In the very HPSD-RFA group an additional control was available on the ablation temperature, which was limited to 60°C. The alarm LET was exceeded in 18 patients, the maximum recorded value was of $42 \pm 2^\circ\text{C}$. Severe adverse events were reported in 1 (2%, vHP-SD) and 3 (6%, control) patients. The study confirms that very HPSD-RFA may induce substantial LET increase.

L. O'Neill et al. [16]

This trial too involved two groups (90 patients each) treated with very HPSD-RFA (90W, 4s) and with lower RF power (35-50W). The LET issue is not discussed, but what matters here is to point out that one esophageal injury (not better specified) occurred in each group.

J. Müller et al. [17]

The emphasis of this paper is on the most appropriate selection of the ablation index allowing to prevent ETLs without reducing the efficacy of HPSD-RFA (50W). Though analyzing LET evolution is not the authors target, the paper points out that precautions have to be taken during HPSD-RFA.

D. Chieng et al. [18]

A comparison between HPSD-RFA (40W) and the low power procedure (25W) performed on 44+44 patients. LET was monitored with an alarm threshold of 38°C, but also LET increasing

rate was taken into account, interrupting power supply when it exceeded 1°C in 5s. This latter detail is rarely considered but is instead remarkable, since an excessive esophagus heating rate is actually a distinctive indicator of a dangerous situation (the S-Cath CIRCA probe was used, though for the specific purpose of detecting the heating rate an even faster probe would have been preferable). Both such alarms took place with comparable frequency in the two groups. Interestingly, 4 ETLs occurred in both group, all classified as superficial ulcerations. The conclusion is that the two procedures are equivalent as far as the risk of ETLs is considered, with HPSD-RFA having the advantage of being shorter. However, for the purpose of the present paper we stress the fact that HPSD-RFA does imply the risk of ETLs and requires LET monitoring not differently from the low power procedure.

Theoretical Papers

A. Fasano, L. Anfuso [19]

A complex mathematical model is employed to simulate the evolution of the thermal field during a typical HPSD-RFA, namely six applications over a PV ostium facing the esophagus (worst case), power 60W, duration 6s, intervals between successive applications 50s. Attention is focused on LET, emphasizing its critical dependence on the patient anatomical configuration. In particular, it is shown that reducing the esophagus-ablator distance by just 1.4mm and leaving the parameters of the treatment unchanged, the maximum LET passes from 39.1°C (for an average anatomical configuration) to 45.8°C. A clear indication emerges about the importance of keeping LET under control and in case of necessity waiting for a suitable LET decrease before resuming RF delivery.

A. Fasano [20]

Here the answer is provided to a very simple question. Assume that the typical ablation temperature is kept at the ablation site, schematized as a sphere, for the typical application time and consider a distance from the ablator where we suppose we have a thermal sensor. Choose a temperature increment, corresponding for instance to the LET alarm set on the probe. How long does the temperature at the chosen location take to undergo the chosen increment?

In this simple setting, the thermal field can be calculated explicitly and it becomes easy to find the requested time. Not surprisingly, we find out that such a critical time is of the same order as the application time. Though this kind of approach is naïve, since it disregards for instance the medium inhomogeneity and blood flow, it leads very quickly to understand how effective heat conduction is and how fast LET can be affected.

Discussion

We have examined recent papers (both clinical and theoretical) considering LET evolution during HPSD-RFA. Our aim was not to assess the efficacy of such a procedure, nor to compare it with the traditional RFA procedure (which was the main goal of the quoted clinical papers), but rather to draw attention to the question emerged among electrophysiologists of whether or not LET monitoring is actually necessary during HPSD-RFA. Based on the evidence collected here, the conclusion is that shortening application time when applying high RF power does not prevent heat to reach the esophagus and produce a LET increase which can be quite substantial, possibly leading to ETLs. Hence the necessity of LET monitoring. Of course, this is also

an indication that the heat delivered may produce other collateral damages: for instance, gastric hypomotility is an alarmingly frequent complication in HPSD-RFA. We add one more consideration: thermal variations are faster when high power RF is delivered, a delicate aspect, not enough emphasized in the literature. In the paper L. Anfuso et al 2018 [21] it was shown that, even for the traditional RFA procedure, monitoring LET with sensors that are not fast enough can lead to dramatic situations in which the actual LET behavior is completely out of control. Clearly, when dealing with HPSD-RFA the rapid response of thermal sensors is a mandatory characteristic.

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