Risk zone evaluation for modern technology of varicose veins radiofrequency thermal ablation

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Abstract A widely used radiofrequency ablation technology for varicose veins treatment is accompanied by a high incidence of the adjacent nerves injury in a “risk zone”. “Risk zone” term characterizes the region near the vein of the irreversible damage to the nerves and other structures. The mathematical numerical modelling of the propagation of heat emitted by the catheter on the vessel wall was performed using the differential heat equation. It was shown, that at the 20th second of standard radiofrequency ablation cycle the boundary of "risk zone" is located at the distance of 0.38 mm from the vein surface according to the mathematical model of RFA regimen proposed for the first time. The solution injecting under ultrasound surveillance in an amount sufficient to exceed a thickness of 0.38 mm around the vein has been recommended.

1. Introduction
Currently, there is a wide range of thermal ablation technologies for removal of varicose veins (VV). One of the most common of them is a radiofrequency ablation (RFA). Its efficiency for varicose vein removal is up to 97% [1]–[3]. The thermal ablation methods are associated with fewer complications and shorter postoperative period compared to surgery [1], [4]. Nevertheless, an excessive thermal damage which is going beyond VV can injure nearby nerves. Nerve injury is a complication that causes disturbances of sensitivity in up to 30% of cases [5]–[10]. To avoid sensitivity disturbances, VV should be separated from adjacent tissues (including nerves) by a layer of a solution containing anesthetic. The injection is provided by a surgeon with a needle; the solution is pumped along VV under ultrasound surveillance as close to the vein wall as it possible.

The manufacturer of the mostly used equipment for RFA recommends injecting 1 ml of the solution per 1 cm along the vein [3], [11]. However there are no published studies that would establish minimal quantity of this solution or thickness of the solution layer enough for nearby structures protecting during one standard 20-second RFA cycle. The temperature above 60°C is needed for protein coagulation within vein wall, but outside of the vein surface, the same temperature causes nerves injury [12]. “Risk zone” term characterizes the region near the vein of the irreversible nerves and other structures damage. The aim of this study is to calculate the minimum thickness of the solution layer that prevents the nerves injury.
2. Methods

2.1. Preliminary data harvesting
The experimental data of temperature dependences on time on the surface of the catheter placed inside the vein during RFA was taken as initial data in the model. These temperature-time profiles were obtained in a private clinic "Medalp" (St. Petersburg). Video records of 30 RFA procedures from VNUS generator display readings were analysed second by second. The information was received and processed by parametric statistics method. Consequent patients with a diameter of the VV up to 6 mm were included in the research. The mean solution amount that was injected during observed procedures consisted 7.4 ml/cm of the vein.

2.2. Geometric model
The VV is considered as a tube with the thickness of 1 mm that tightly covers cylindrical catheter. In our model, a layer of solution evenly surrounds the vein and forms a tube with the infinite thickness around her. The vein and catheter are in isotonic NaCl solution. The geometric model of the studied system is shown in the figure 1. All sizes are given in cylindrical coordinates where: \( R = 1 \) mm – the inner radius of VV / outer radius of catheter; \( L = 7 \) cm – the working length of the catheter; \( h = 1 \) mm – the wall thickness of the vessel; \( B = \infty \) – the thickness of the solution layer.

![Figure 1. Geometric model of the studied system: 1 – catheter, 2 – blood, 3 – NaCl solution, 4 – vessel wall; R – inner radius of the vein / outer radius of the catheter, L – catheter length, h – vessel wall thickness, B – thickness of the NaCl solution layer.](image)

2.3. Mathematical model
The task of the propagation of heat emitted by the catheter on the vessel wall modeling was solved numerically using the differential heat equation [13]:

\[
C_p p \frac{\partial T}{\partial t} + \vec{u} \cdot \nabla T - k \cdot \nabla^2 T = Q. \tag{1}
\]
here $T$ - temperature; $t$ - time; $p$, $C_p$ and $k$ - density, specific heat capacity and thermal conductivity, $u$ - velocity of blood in the vessel, $Q$ - energy generated by the catheter during RFA. Assuming that the catheter is fixed, the vein walls are rigid, homogeneous and isotropic, the equation (1) takes the form:

$$C_p p \frac{\partial T}{\partial t} = \frac{\partial}{\partial z} \left( k \frac{\partial T}{\partial z} \right) + \frac{\partial}{\partial r} \left( k \frac{\partial T}{\partial r} \right) + \frac{k}{r} \frac{\partial T}{\partial r}$$  \hspace{1cm} \text{(2)}$$

here $z$ and $r$ are longitudinal and radial coordinates of the cylindrical coordinate system. It was assumed, that the values of the parameters used in the model [14], [15] do not have the dependence on the temperature to simplify the modeling. Equations (2) were solved in the 2, 3 and 4 areas (that is, outside the region occupied by the catheter, figure 1) using finite element method [16]. The COMSOL Multiphysics 5.1 software package was used for calculations [17].

2.4. Data interpretation

The so-called "risk zone" term has been introduced in this research to simplify the analysis of RFA procedure safety. So, the "risk zone" defines region near VV at which the temperature reaches more than 60°C during RFA procedure and leads to irreversible damage of nerves and other structures surrounding VV.

The thickness of the solution layer in the case of 1 ml of the solution per 1 cm of the vein introduction, according to recommendations [11] have been calculated. It was assumed that the distribution of the solution around the VV was uniform. For calculations the model with 2 cylinders was used: an internal (venous vessel) cylinder with the radius of 2 mm and external cylinder (volume of the solution) with finite unknown radius $x$. The difference between the volumes of these cylinders is a recommended solution volume. The height of the cylinders was set equal to 10 mm, that’s why, it is possible to operate not with volumes of the cylinders, but squares of cylinders cross-section. That is, the recommended square of cylinders cross-section has been obtained by dividing the recommended solution volume of 1 ml =1000 $\text{mm}^3$ to cylinder height of 10 mm. Thus, the difference between the cross-section of the external and internal cylinders is 100 $\text{mm}^2$ and the radius of external cylinder constitutes 6 mm. Further, the value of the thickness of the solution layer was determined as a difference between the external and internal radiuses of considered system.

3. Results

The recommended thickness of the solution layer has been calculated using the information about the needed solution volume (1 ml per 1 cm of the vein) from the manufacturer guidance. The method of using the difference between the volumes of two cylinders, corresponding to VV and VV with the solution, provides reliable single-valued results due to simplicity of chosen model. Thus the value of solution layer thickness has been constituted 4 mm.

The temperature-time profiles for the surface of the catheter, middle and outer surface of the venous wall were designed for the 20-seconds cycle of the radiofrequency exposure, according to the standard mode of the widely used technology - VeneFit (Figure 2). According to the figure 2 (black line) the vein wall outer surface heating exceeds 60°C at the 9th second of RFA cycle, which can lead to the damage of structures, located in the vicinity of VV and consequently can be cause of the the sensitivity disturbance.

The distance between the vein surface and the isotherm of 60°C near the VV is the "risk zone" depth (Figure 3). At the 20th second of standard RFA cycle the boundary of "risk zone" is bounded above at the distance of 0.38 mm from the vein surface.
4. Discussion

We have made the calculations for the thickness of the solution layer, injected around the vein, with an assumption about the uniform distribution of the solution. However, in medical practice, the distribution is uneven. That's why the injection of a larger solution amount is necessary for obtaining a desirable minimum thickness of its layer. Thus, the solution injecting under ultrasound surveillance in an amount sufficient to achieve a thickness of the solution all around the vein not less than 0.38 mm is suggested, accordingly to our results.

Further, the thickness of the solution, recommended by the manufacturer, making the simplest mathematical calculation has been defined. This value is 4 mm. Our observation is that surgeons use to inject much more amount of the solution for the lack of the information about the minimal border of so-called "risk zone" for preventing damage to nerves.

The "risk zone" depth obtained in our model is about 10 times less than the solution layer recommended by manufacturer. Our calculations showed that the "risk zone" of nerve injury is relatively thin and can be easily overlapped by the recommended solution quantity. Thus, the nerve injury after the procedure should be explained by quality rather than quantity of the solution injections. It is recommended performing the solution injections between the vein and nerve near the vein wall under the high-resolution ultrasonography.

To avoid the nerve displacement back to the vein due to the leakage of the solution, it is recommended segment-by-segment injecting, starting from the proximal segment immediately before each 7 cm of thermal ablation, rather than cover the entire vein in advance as it is accepted to do. In the case, where the distance of 0.38 mm between the vein and nerve cannot be achieved with the help of solution, it is recommended withholding from thermal ablation of this vein segment.

It is possible to eliminate the risk of complications completely by modifying the temperature-time mode of RFA to reduce hyperthermia around the vein to a safe level for nearby tissue. In this case, when the boundary of the "risk zone" aren’t go beyond the vein wall, it is possible to carry out RFA of vein tightly cuddled to the catheter (due to the initially small diameter or spasm, or by increasing the diameter of the working catheter element) entirely without solution under short-term intravenous anaesthesia.
5. Conclusion
It was shown, that at the 20th second of standard radiofrequency ablation cycle the boundary of "risk zone" is located at the distance of 0.38 mm from the vein surface according to the mathematical model of RFA regimen proposed for the first time. The solution injecting under ultrasound surveillance in an amount sufficient to exceed a thickness of 0.38 mm around the vein has been recommended.

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References
[1] Wittens C et al. 2015 Editor’s Choice - Management of Chronic Venous Disease: Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS) Eur. J Vasc. Endovasc. Surg. 49(6) 678–737
[2] Treatment of Superficial Venous Disease of the Lower Leg Guidelines 2015 (American College of Phlebology)
[3] Goodyear S J and Nyamekye I K 2015 Phlebology 30(2) 9–17
[4] Varicose veins: diagnosis and management (NICE Clinical guideline) 2016
[5] Choi J H, Park H–C and Joh J H 2013 J Korean Surg Soc 84(2) 107–13
[6] Rasmussen L H, Lawaetz M, Bjoern L, Vennits B, Blemings A and Eklof B 2011 Br. J. Surg. 98 1079–1087
[7] Proebstle T M et al 2011 J. Vasc. Surg. 54(1) 146–152
[8] Tolva V S, Cireni L V, Bianchi P G and. Casana R M 2013 Surg Today 43 741–744
[9] Bisang U, Meier T O, Enzler M, Thalhammer C and Husmann M 2012 Phlebology
[10] Park H S, Kwon Y, Eom B W and Lee T 2013 J Korean Surg Soc 84 48–56
[11] Reference Guide For The Venefit Procedure
[12] Sengupta R P and Stundon R J 1977 Br Med J 6054 142–3
[13] Carslaw H S and Jaeger J C 1959 Conduction of heat in solids 2nd ed. (London: Oxford University Press)
[14] Choi S Y, Kwak B K and Seo T 2014 Comput Math Methods Med 485353
[15] Shadrina E M and Volkova G V 2009 Determination of thermal properties of gases, liquids and water solutions of substances (Ivanovo: Ivanovo State University of Chemistry and Technology Publ.)
[16] Jain M K and Wolf P D 2000 Ann Biomed Eng 28(9) 1075–84
[17] COMSOL Multiphysics 2016 (COMSOL Inc)