

Prerequisites for Developing New Generation Cryosurgical Devices (Review)

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The study represents the implementation areas, key advantages and application problems of a cryotechnique in recent times, as well as the classification, the main characteristics and disadvantages of the existing cryosurgical units. The review considers the prerequisites for developing new generation cryosurgical units. Among them there were distinguished five main research lines. The first line is the development of a high-precision cryotherapy dosing technique. The second line is related to the formation of prediction and result control techniques of establishing a predetermined cryonecrosis area, since practice requires a detailed calculation of a procedure to choose the modes of cryosurgical devices, which meet the dosing conditions. The third line is the study of thermal properties of biotissues in a wide temperature range (including pathologically altered tissues), as well as their modification to improve cryotherapy quality. The fourth line is the improvement of control cryotherapy methods. Work automation of the elements of cryosurgical devices and the diagnostic support on a real-time basis are necessary. It enables to provide a surgeon with a complete presentation. The fifth research line is connected with the creation of cryosurgical robotic technologies. Robot-assisted medicine has widespread application, it becoming more technically and medically advanced. Robotic technologies open great challenges for future development of the entire branches of clinical medicine including cryosurgery.

The problem of insufficient opportunities of cryosurgical units to meet the medical and technical requirements is found to be related to the lack of control procedure options rather than the imperfection of equipment technical characteristics. To achieve a high efficiency of cryotherapy, the problem is to be solved comprehensively. The development of medical imaging technologies, computational power and equipment maintenance of the technique can make it possible to extend significantly the functionality and application area of cryosurgical apparatuses so that in the future to increase the competitive capability of a cryotechnique.

Key words: cryosurgical equipment; cryomedicine; cryotechnique; cryotherapy; cryosurgical devices.

Medical cryotechnologies have widespread application in the surgery of benign, malignant lesions, as well as mucosa. Moreover, a low-temperature effect is successfully used in dermatology and cosmetology, pediatric surgery, gynecology, neurosurgery, ophthalmology, otolaryngology, dentistry, veterinary

medicine, proctology and other fields of medicine, when some biotissue volume is to be destructed [1–9].

Cryosurgery competes with a variety of technologies: radio-frequency, microwave, laser, ultrasound, robotic, traditional ablation, and their combinations [10]. In various special cases these technologies

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serve as methods of choice, however, they are not infallible. In course of time technologies are changing: the procedures are being improved physically and biologically, the practical application experience being generalized, recommendations being developed, advanced materials and information technologies being implemented, new equipment models being mastered. Accordingly, their disposition in practical application spheres is changing.

Currently, a cryotechnique is promising as an alternative method, when minimum damage of a tumor surrounded by intact tissues is needed [11, 12]. There is a notable advance in cryosurgery application combined with preliminary SHF-heating in hemangioma therapy [13–17], as well as in urology [11, 18–20].

Among the advantages of cryosurgery there are the following: easy to perform; compatibility with therapy and surgical interference; bloodless and painless; relatively rapid regeneration and a good cosmetic effect; an immune-stimulating effect; a potential broad range of exposure areas; applicable in elderly patients and in case of comorbidities, a short hospital stay [1, 17, 21, 22].

The limitations of the technique are: complexity of prognosis and control of cryonecrosis borders; perifocal edema; necessity and maintenance of cryoagent supplies; information gap in methodology and insufficient integrating recommendations (special cases are mainly considered) [1, 22].

Surgery costs, which currently depend heavily on cryosurgical apparatuses (CSA) used, compete for attention. Costly modern stationary units with disposable component parts significantly raise their price. CSA models conceptually designed in the 80s of XX c. are morally obsolete; however, due to single-unit production they are relatively costly.

The main constraining development factor for cryosurgery is the lack of CSA meeting current medico-technical requirements in full measure [1]. Theories of operation are developed on the basis of CSA capacities available. The first generation cryosurgical equipment appeared in 1960s, liquid nitrogen primarily being used as a cryo-agent. Compressed-gas-based equipment was developed in 1990s. It enabled to miniaturize an instrument. Then there emerged the opportunity to accompany ultrasonic image operations [19]. Modern CSA can be classified by dimensions (hand-held portable, hand mid-size, stationary) and by cold source used (liquid nitrogen, nitrous oxide, carbon dioxide, high-pressure gaseous argon, as well as thermoelectric).

Hand-held portable (weight with a cryo-agent can be to 0.5 kg) and hand mid-size CSA (to 1.5 kg) structurally are made in a single case. A cryo-instrument (an operating tip, cryoprobe) and the case in a stationary CSA (to 50 kg) are made separately, due to which stationary units have longer cooling duration and higher power, and a number of optional functions (a control board and software, temperature control and emergency cooling, etc.).

A group of hand-held portable CSA include: KM-01, KM-02 (MKNT, Russia), CryoPen (H&O Equipments, Belgium), CryoStick (Cryotec, Russia), AK-cryomed (MED-CRYONICA, Russia), Cryoalfa (SKAFTE medlab AB, Sweden), Verruca-Freeze (CryoSurgery Inc., USA), Histofreezer (OraSure Technologies, USA), Erbokryo 12 Cryo Gun (ERBE Elektromedizin, Germany) and others. These CSA are used mainly for cosmetic purposes, for cryo-destruction of surface lesions [23–27].

A group of hand mid-size CSA involve: KMT-01 (Cryomedical Technologies, Russia), Cryolney (Cryotec, Russia), Kryotur 600 (GymnaUniphy, Belgium), Cryoton (Medan, Ukraine), KS-2 (KrioSystem, Poland), Cryospray CS1 (SMT, Check Republic), CryoSkin (Cryo Diffusion, Italy), etc. There are mid-size CSA with biotissue temperature control: Cry-Ac+ (Brymill, USA), KCH 450 Automatic (SMT, Check Republic), which have an infrared temperature sensor (it enables to monitor surface temperature, with the exception of the layers in deep biotissue).

There are highly specialized stationary units: CryoStar (D.O.R.C., Holland), IceSense3 (IceCure Medical, USA), Visica 2 (Sanarus medical, USA), CryoConsole Cardiac (Medtronic CryoCath, Canada), CryoMaze (ANS Medical, USA) and the apparatuses developed for extensive use: SeedNet, Visual-ICE, Presice, SeedNet MRI (Galil Medical, Israel), CRYO-01 “ELAMED” (Elatomsky Instrument Plant), medical cryotherapeutical system MCS (International Cryomedicine Institute, Russia), CRYO-S (Metrum Cryoflex, Poland), Cryo-S (SMT, Check Republic), CRYO-MT (Med-Technology, Russia), ERBOKRYO CA (ERBE Elektromedizin, Germany), CRYOCARE CS (Endocare, USA), KRY-10 (Uzumcu, Turkey), DNEPRO-CRYO (Dnepro-MTO, Ukraine), etc. Modern stationary CSA models operate under a computer program control, and maintain the usage of up to 25 penetration cryo-instruments. Among them just some models have biotissue temperature feedback, i.e. there is the opportunity to control cryotherapy dosing, at least partially, in some points of a target area, and not only visually.

Recently, the following cryo-agents are most frequently used: liquid nitrogen (boiling point is 77.4 K), nitrous oxide (boiling point is 184.6 K) and argon (a temperature in a cryo-instrument reaches 130 K load-free). The systems based on Joule–Thomson effect (compressed gas) are preferable than liquid nitrogen by its cost, mobility and the capability of more precise temperature control, therefore they have obtained a wide circulation in clinical medicine [18, 28]. It was caused by the emergence of minimally invasive cryo-instruments with available argon pressure up to 240 bar. However, such CSA primarily have only a penetration cryo-instrument, while CSA based on liquid nitrogen also have a contact instrument and spray diffusers.

Currently, in Russia, there being applied the nitrogen cryosurgery technologies developed as early as in USSR, and some foreign equipment models are used as

well, e.g., multiple probe minimally invasive cryosurgery technologies are being introduced, mainly, in urology [11, 29]. However, to a large extent, cryosurgery does not find its application in our country. It relates, for the most part, to CSA imperfection resulting in the fact that medico-technical requirements are not fulfilled in full measure, the main disadvantages of a cryotechnique being formed. Moreover, in the surgery concept for the future [30, 31] a low-temperature method is considered as that having a potential for development. To achieve the potential we need to design a new generation CSA, which is impossible without solving some scientific and technical problems. These problems can be presents as the following five lines.

The first line is to develop highly-precise techniques for cryotherapy dosing.

One of promising variants is to use a cryoprotocol: a detailed description of a procedure a doctor is to carry out using CSA. The main objective of cryosurgery is to destroy pathological biotissue within a target area without damaging intact tissues located outside the area. Therefore, dosing cryotherapy needs an exact description of a required cryonecrosis area.

There are some complementary explanations of a cryonecrosis area formation mechanism [10, 17, 21, 32–37]. According to the study [17], biotissue cryodestruction process includes two stages: primary damage (primary cryonecrosis) related to the immediate cell destruction under a low-temperature, and the secondary damage (secondary cryonecrosis) is due to biotissue death resulted from impaired hemodynamics and aseptic inflammation.

In primary destructions, a decisive factor is a thermal flow (extracted from biotissue), but in practice the indicator of cryonecrosis area formation is the temperature fields, which indirectly describe cooling modes [17, 38]. Moreover, it is necessary to be guided by a temperature of biotissue rather than an instrument.

Data on biotissue temperature change are suggested to be used as an indicator of cryotherapy safety and efficiency, in a form of a cryoprotocol. The protocol is to contain all data on biotissue temperature changes during cryotherapy, and is to be divided into separate parts for sequential analysis of a process [39, 40]. According to the work [33], optimized cryoprotocols should take into consideration cryotherapy time, cooling rate, temperature gradient, a number of cryoprobes, as well as contribute to the operation time reduction, destruction of the entire area minimizing the operation cost and the damage of surrounding intact tissues. Dose numerical values (biotissue temperature in space and in time) and a target cryonecrosis area, which is usually of a compound shape, are predetermined within the framework of a cryoprotocol. Other dose variants providing the combination of the necessary conditions of cryotherapy and CSA capabilities are also possible.

The constituents of a cryoprotocol and the examples of their standard values:

1. Biotissue cooling rate is to be provided within a certain range. For instance, according to the study [41], relatively fast freezing at a rate of 40–50°C/min is optimal. Ultrafast freezing is unreasonable, since amorphous ice formed has no damaging effect on cell components. The fact should be borne in mind that the quickest cooling occurs near the cryo-instrument, and the rate decreases far away. For example, cooling at a rate of 50°C/min occurred near the cryo-instrument, while at a 1-cm-distance the rate was 10–20°C/min [42].

2. For cryonecrosis, the biotissue temperature is to achieve a critical threshold, which is various for different cell types within a required cryonecrosis area (minimum target temperature). It is widely accepted that resultant biotissue temperature for primary cryonecrosis in oncological pathology (the most common type) is to be in a range from –40 to –50°C [33, 41, 43]. However, it is significant to take into account that cryonecrosis temperature in different tissues varies considerably, e.g. from –2°C (an osteocyte, dog bone) to –70°C (adenocarcinoma in a rat) [44]. Single cells survived can be preserved up to about –100°C [45].

It should be mentioned that a freezing area is always smaller than a necrosis area. According to the monograph [1], a necrotic zone is usually 1.28 times as small as a freezing area. Judging by the study [46], when biotissue is frozen, a central zone of complete cell necrosis is formed, it being surrounded on the periphery by a cell damage area. The described phenomenon is of great clinical significance, since hyperechoic border of “an icy ball” is imaged at the temperature from 0 to –2°C. In this regard, for adequate biotissue ablation the “icy ball” border should go beyond the area of a planned necrosis [19].

3. The more exposure duration at a minimum temperature, the more expressed destruction in tissues, however it being limited by the cryo-agent amount in CSA and other factors of the procedure in practice [1].

4. A temperature rise results in a harmful effect of high electrolyte concentration on cells [43]. Biotissue warming rate at 10–12°C/min provides the safest cell destruction. In practice, ambient defrost is also recommended.

5. Multiple freezing-defrosting is used (at least a double cycle). The approach is found to be more effective than a single procedure [47–49]. And lower temperatures can be achieved in a cooled biotissue than when it is first frozen. Biotissue exposed to freezing and defrosting enhances its thermal conductivity by 10–20%. In freezing-defrosting, thermal conductivity keeps increasing [43]. Practice shows that in multiple cryotherapy (at least three times) necrotic zone sizes can be larger by 20–25%, than in single exposure.

6. When dosing, it is necessary to take into consideration the secondary damage factors. They are derivatives of temperature change in the exposure area, and enable to increase a necrotic zone. It is noteworthy that a cryotechnique is combined with other modalities (e.g., cryochemotherapy [50]).

The second line is related to the prognosis of providing a cryonecrosis zone, since cryosurgical practice suggests a demand for a detailed procedure calculation to search CSA modes meeting dosing requirements.

Both safety and the efficiency of cryosurgical operations depend on the accuracy of a dose provided. A non-optimal instrument position can lead to the uncovered areas in the exposure zone, the surrounding intact tissue being damaged. The situation is certain to contribute to postoperative complications and, ultimately, resulting in the reduction of therapy quality and its increased cost. In each case of cryotechnique application, it is necessary to calculate an optimal cryo-dosage, which depends on cryo-effect localization and CSA used.

Development of computer programs for dosing simplification, cryo-effect prognosis and control is promising. Software can be used to find an optimal place for cryo-instrument location, a choice of an applicator, cryotherapy duration, a number of repeated freezing and defrosting sessions, etc. [11, 32]. In addition, there will be developed the technologies of virtual environment to simulate surgeon's activity and perform training [31, 51–55].

The problem solution is just at the first set-out. There is the information about the programs of biotissue cryonecrosis prognosis and optimization being under development [12, 22, 51–54, 56–63]. In practice, Visual-ICE (Galil Medical, Israel) apparatus has the most functional program. No similar programs of stepwise computer scheduling, which includes a full-scale thermal calculation of a target dose, have been found in modern literature. The exposure dose is usually based on methodological recommendations.

The works [42, 58–60, 64–69] have considered different options of a simplified Stefan's problem solution in prostatic cryo-ablation, and the variants to optimize cryo-instrument position, the prognosis of thermal fields in real-time mode based on the data on biotissue structure obtained beforehand by medical imaging, the issues of modeling accuracy, cooling capacity, techniques for calculation geometry and finite element grid, invasive and non-invasive thermometry technologies. However, to achieve a stable and accurate result, it is necessary to carry out a number of sub-studies including those to obtain typical data on temperature fields and to have an opportunity to calculate heat fields on different human body areas immediately prior to an operation.

To provide accurate cryotherapy dosing, the following sequence is suggested. Considering the capabilities of the equipment available in a clinic, it is reasonable to calculate a dose preliminarily using medical imaging information on a structure of a certain target cryonecrosis area. A calculation is to result in obtaining cryotherapy parameters. Further, carrying out a procedure in order to control necrotic zone formation it is possible to combine the data on prognosis, temperature sensors and medical

imaging in real time mode. Moreover, it is possible to automatically position a cryo-instrument in coordinates related to prognosis and imaging.

Currently, there are two approaches to the development of cryotherapy result prognosis techniques: an experimental technique and a mathematical model method. An experimental technique [1, 11] enables to obtain objective data on thermal fields in biotissue, the sizes of necrosis and freezing zones in a form of tables, graphs, calculation charts, master curves. However, it has its limitations related to a high cost of an experiment, difficulty in consolidating the information gained on a certain object, and transferring it to other objects, which differ in size, thermophysical properties, etc. The capacities of an empirical approach are limited, since biological objects are diversified and compound, the cryotherapy modes being various, and there are a lot of factors affecting the process.

Cryodestruction computer modeling based on explicit diagnostic data on calculation system composition and biomaterial thermophysical properties close to reality will allow describing the processes during the procedure. Modern computer modeling means enable to calculate non-stationary thermal fields inside biotissue in case the borders, initial conditions and biotissue thermophysical properties are well established. By solving a problem of 3D heat transfer during cryosurgery we can numerically optimize a cryosurgical operation protocol [44, 70].

However, currently, computer thermophysical cryosurgery simulation is not developed enough to be applied adequately in practice: it does not enable to describe precisely a body response to cryo-effect, calculate a necrotic zone, and requires perfect knowledge of thermophysical properties of biotissue, real characteristics of cryo-instruments, and is to consider a complex nature of biological tissue at micro- and macro-level [71–74]. Moreover, the technologies for obtaining calculation geometrical model using medical imaging data segmentation are insufficient [53, 75–77]; there is difficulty in solving Stefan's problem in relation to computation power that requires the development of simplified calculation algorithms; the given examples of thermophysical modeling of different body areas are not sufficient either.

The most rational approach to the development of cryotherapy result prognosis techniques is the combination of these two methods: mathematical modeling in extended and objective experimental verification on real biological objects [1].

The third research line is the study of thermophysical properties of biotissues in a wide range of temperatures (including pathologically altered tissues), as well as the change of their properties exposed to external factors to improve cryotherapy results.

Biotissue is a multi-component, capillary and porous, moisture-laden, anisotropic body consisting of several layers with essentially different thermophysical properties. Adequate results of thermophysical

calculations can be achieved only if considering real properties of biotissue: complexity, anisotropy, dependence on a temperature and the rate of its change. There are databases on thermophysical properties of biotissues, for instance in the studies [1, 78]. Neither full-scale analysis nor systematization was carried out.

In practice, there is a common situation when a cryo-effect should cover several layers of different biotissues at once to destroy a mass lesion, a thickness of each layer depending on a mass localization, and human individual characteristics: age, body mass, height, etc. The differences in thermophysical properties of biotissues do not make it possible to create a universal tool appropriate for all procedures with biotissues. Basic cryosurgical apparatuses and instruments should be developed for a certain area and used in specific pathologies. Currently, there is insufficient data on thermophysical properties of biotissue both in health and none. Moreover, there is a lack of methodological information on measuring thermophysical properties of biotissues in a wide temperature range. Modern measuring methods [79] are noticed to neglect biotissue characteristics.

Low thermal conductivity and high thermal capacity in some cases negatively limit the capabilities of a local thermo-exchange. In this situation it is reasonable to have an effect on biological tissue properties by modifying it. In the work [80] the authors pay their attention to the possible use of such agents in the future, the agents enhancing the tumor sensitivity to destruction through freezing (the so called cryosurgery catalysts). In addition, it is necessary to implement the techniques to enlarge a freezing zone by preliminary application of ultrasound, SHF [81, 82].

For adequate control of cryo-effect quality there have to be chosen control points for temperature measurement in order to hold the adequate data to check protocol performance. It should be noted that with moving away from a freezing point, a freezing zone demonstrates the growth of ice crystals due to eventual decrease of freezing frontal advance rate. The fact proves the supposition that in a target area there should be several points to control the process parameters [17].

The fourth line is to improve cryo-effect control techniques. There should be the automation of CSA operating elements and a real-time diagnostic support of an operation, which enable to provide a surgeon with complete data on a situation [83–85]. It is advisable to combine the data on cryonecrosis prognosis and the perioperative findings of medical imaging and thermal sensors.

One of the main vectors of cryosurgery development is monitoring and control of a freezing area and a necrotic zone in real-time mode (frequently used in multi-probe minimally invasive cryosurgery [11, 86]). A temperature in the target area is controlled, for example, by transrectal ultrasound showing an ice formation area.

Thermocouples are placed in most significant points. However, both: ultrasound, and thermocouple do not offer the opportunity to control temperature at any point that can result in falling short of necrosis temperature in a target organ or biotissue, as well as intact tissue damage in a surrounding area.

Modern temperature measuring methods can be divided into invasive and non-invasive. Invasive techniques (measurement at a certain body organ point) and non-invasive surface temperature measuring are the most advanced. In practice, the frequently used thermocouple is copper-constantan built in a cylindrical body, 1.5 mm in diameter, is in cryoprobes [61]. The development of technologies for using a set of tiny wireless implantable temperature sensors is considered promising [62]. There being carried out the investigations on noninvasive thermometry based on electromagnetic fields for cryodestruction [87–89]. The information mentioned can suggest that thermophysical simulation in abundance of data on biotissue temperature will be irrelevant. However, on the contrary, modeling completed with the information on biotissue temperature at some points (feedback formation) can be the most accurate and quick. And with the help of calculation we can receive data on temperature in intermediate points. As a result, extended application of temperature measurement technologies completed with special algorithms can raise the quality of cryotherapy result prognosis to a high level compared to their separate application. It should be taken into account that cryotherapy control data can be used to develop cryotherapy techniques [90].

The fifth research line is related to the development of robotic cryosurgical technologies. Robot-assisted medicine has a widespread application, and keeps developing becoming more sophisticated from medical and technical point of view. Robotic technologies offer challenges for further development of clinical medicine branches [91, 92].

There are many definitions of a concept “robot”, one of them combines the following functions [88]: a capacity to carry out certain actions, a programmed-based ability to solve various tasks, capacity to interpret and modify the answer to operator’s commands. Robotic systems can be used for precise positioning, combining imaging data, operation prognosis and control, a procedure being performed under the surgeon’s control [30, 93–97]. For instance, the work [80] emphasizes the possibility to combine cryosurgery with a robot-assisted console. It is facilitated by the fact that a minimally invasive penetration access requires no sophisticated artificial intelligence and can be guided by a step-by-step surgeon’s inspection.

Next generation stationary CSA can be based on an algorithm based on an individualized medicine concept. A health care professional provides the preparation for a surgery, and assigns a cryotherapy dose in the software, and provides medical imaging data on a target biotissue zone. After calculating a dose, according to the capacities

of CSA, a health care professional studies and corrects the results, making a decision about a procedure start and regimen. After that a surgeon introduces a cryo-instrument. CSA performs cryotherapy automatically under a visual control of a health care professional. The approach enables to reduce surgeon's mechanical work, and much attention is paid to correctness of a procedure course, and due to this, a time for a specialist training and his qualifying can be decreased.

A cost reduction is one of the main factors for cryosurgery development. Modern surgical techniques using robot-assisted systems and physical factors can compete to the utmost with traditional methods provided that equipment cost and its technical support will not influence significantly the operation cost, and the implementation of techniques at the local level will not be a long process, the techniques themselves being recommended as methods of choice.

Unification and large-scale involvement, which directly depend on flexibility in application, will make cryosurgery available. For this purpose, it is necessary to develop universal basic equipment with a wide choice of specialized instruments. On the one hand, it is essential to develop easy-to-operate, portable hand CSA, which serve primarily for outpatient departments, where a great variety of specialized cryo-instruments and application-dependent software to calculate cryo-exposure, as well as the use of new materials should be provided [26, 98, 99]. On the other hand, it is necessary to develop reliable, relatively productive basic stationary CSA [13, 100, 101] including those with the elements of robotic application. As far as a cryo-agent is concerned, argon is considered to be the most promising one. Compared to liquid nitrogen, in a single cryo-instrument with argon the power is lower, and in addition, it is compact and enables to apply a group of cryo-instruments [102, 103]. There is a single example of minimally invasive penetration instrument running on liquid nitrogen. It is medical cryotherapeutic system MCS (International Cryomedicine Institute, Russia), though the manufacturer does not indicate cooling capacity of the apparatus [104–106]. Special attention should be paid to the availability of automatic compressed gas control compared to boiling cryo-agent.

Conclusion. The problem of inadequate capabilities of cryosurgical apparatuses to meet medico-technical requirements is currently related to insufficient procedure control capabilities rather than the imperfection of characteristics of the apparatuses themselves. To reach a high efficiency of cryotherapy, the problem is to be solved in an integrated manner. The development of medical imaging technologies, the increase computation capacities and the equipment advancement to provide a low-temperature technique will enable to expand functionality and the application sphere of cryosurgical units in future.

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