Transcutaneous laser therapy for hematopoietic adverse effects of antineoplastic chemotherapeutics: Randomized clinical trial

RESUMO | Objetivo. Avaliar a eficácia dos protocolos de aplicação transcutânea do Intravenous Laser Irradiation of Blood 30' e 60', sobre os efeitos adversos no tecido hematopoiético por agentes quimioterápicos antineoplásicos endovenosos em adultos. Método. Ensaio clínico, randomizado e unicego, realizado em serviço ambulatorial de quimioterapia de hospital público do estado de São Paulo realizado de abril de 2018 a março de 2019. A amostra constituiu de 55 pacientes com tumores sólidos, a partir do segundo ciclo de tratamento com fármacos endovenosos citotóxicos para o tecido hematopoiético. O comprimento de onda utilizado foi de 660 nm, por via transcutânea, sob artéria radial. Resultado. Comparado ao tipo de hemocomponente, obtivemos, respectivamente aos protocolos do Intravenous Laser Irradiation of Blood 30' e 60': hemoglobina (85%; 86%), plaquetas (100%; 100%) e neutrófilos (95%; 92%). Conclusão. Considerou-se ambos os protocolos eficazes e, portanto, sugere-se implantá-los em unidades de quimioterapia.
Descritores: Terapia a laser; Administração cutânea; Efeitos colaterais e reações adversas relacionadas a medicamentos; Quimioterapia combinada; Enfermagem.

ABSTRACT | Objective: To evaluate the effectiveness of the protocols for transcutaneous application of the Intravenous Laser Irradiation of Blood 30' and 60', on the adverse effects on hematopoietic tissue by intravenous antineoplastic chemotherapeutic agents in adults. Method. Clinical, randomized and single-blind trial, carried out in an outpatient chemotherapy service of a public hospital in the state of São Paulo, carried out from April 2018 to March 2019. The sample consisted of 55 patients with solid tumors, from the second cycle of treatment with cytotoxic intravenous drugs for hematopoietic tissue. The wavelength used was 660 nm, transcutaneously, under the radial artery. Result. Compared to the type of blood component, we obtained, respectively from the Intravenous Laser Irradiation of Blood 30' and 60' protocols: hemoglobin (85%; 86%), platelets (100%; 100%) and neutrophils (95%; 92%). Conclusion. Both protocols were considered effective and, therefore, it is suggested to implant them in chemotherapy units.
Keywords: Laser therapy; Cutaneous administration; Drug-related side effects and adverse reactions; Combined chemotherapy; Nursing.

RESUMEN | Objetivo. Evaluar la efectividad de los protocolos de aplicación transcutánea de Irradiación Láser Intravenosa de Sangre 30' y 60', sobre los efectos adversos sobre el tejido hematopoyético por agentes quimioterápicos antineoplásicos intravenosos en adultos. Método. Ensayo clínico, aleatorizado y simple ciego, realizado en un servicio de quimioterapia ambulatoria de un hospital público del estado de São Paulo, realizado de abril de 2018 a marzo de 2019. La muestra estuvo compuesta por 55 pacientes con tumores sólidos, del segundo ciclo. del tratamiento con fármacos intravenosos citotóxicos para el tejido hematopoyético. La longitud de onda utilizada fue de 660 nm, por vía transcutánea, bajo la arteria radial. Resultado. En comparación con el tipo de componente sanguíneo, obtuvimos, respectivamente, de los protocolos de Irradiación Intravenosa con Láser de Sangre 30' y 60': hemoglobina (85%; 86%), plaquetas (100%; 100%) y neutrófilos (95%; 92%). %). Conclusión. Ambos os protocolos se consideraron efectivos, por lo que se sugiere implantarlos en las unidades de quimioterapia.
Palabras claves: Laserterapia; administración cutánea; Efectos secundarios y reacciones adversas relacionados con los medicamentos; quimioterapia combinada; Enfermería.

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INTRODUÇÃO

It is known that Intravenous Laser Irradiation of Blood (ILIB) promotes blood photobiomodulation, by means of low-intensity laser, directly irradiated intravenously (ILIB), transcutaneously (TLIB and/or modified ILIB) and mucosal (transmucosal and sublingual ILIB). [1,2]

The transcutaneous ILIB stands out for being a safe procedure according to protocol, so as not to produce iatrogenic effects on tissues or the biological system, of low cost, applied to the skin or mucous membranes and, therefore, non-invasive, allowing the absorption of light in the red wavelength by the blood. [3,4,5,6,7,8] This type of therapy favors the physiological dynamics of the organism, promoting tissue biostimulation/healing, reduction of inflammation, analgesia and antimicrobial action. [5]

Studies with transcutaneous ILIB therapy have shown efficacy in blood rheology, with a decrease in viscosity at all displacement speeds, improvement in the viscoelasticity of erythrocytes and their osmotic resistance. [5,6] It is known that this type of therapy interferes with the arachidonic acid cascade (anti-inflammatory effects), increasing the production of prostaglandins, in addition to contributing as antiplatelet aggregation, renal function, the release of neurotransmitters, the increase of mucous secretions and the modulation of the immune function, providing greater fluidity to the blood. [7,8]

In chronic or acute systemic inflammatory processes, research has demonstrated the effect of transcutaneous ILIB treatment in promoting a cascade of biochemical events, such as protein synthesis that triggers cell proliferation and migration, modulation of cytokine and growth factor levels, as well as increased tissue oxygenation. [5,9]

The use of laser therapy in its various forms of application has been spreading little by little in the area of nursing. The most recent COFEN opinion (13/2018) increasingly ensures the introduction of the nursing professional to laser therapy. It is also noteworthy that the qualification for the use of this technology is exclusive to nurses, as they must have knowledge in the areas of physics, biophotonics, interaction of laser and biological tissues, dosimetry, in addition to in-depth knowledge of physiology and rehabilitation. [10]

Accordingly, the objectives were outlined: to evaluate the effectiveness of the 30' and 60' transcutaneous ILIB application protocols, on the side effects in the hematopoietic tissue, caused by intravenous antineoplastic chemotherapy, in patients 18 years of age or older and to observe adverse effects on skin integrity (site of application) of patients exposed to both protocols.

METHOD

This is a clinical, parallel, randomized trial, approved by the Research Ethics Committee (CAAE: 82323318.9.0000.5411, Opinion: 2,512,164) and with the Brazilian Clinical Trial Registry (ReBEC) (RBR – 7y8rtz), performed in an outpatient chemotherapy service at a Public Hospital in the State of São Paulo, Brazil, from 04/03/2018 to 03/29/2019.

To select the participants, the inclusion criteria were: patients aged 18 years or older in exclusive outpatient treatment, without self-reported cognitive impairment by the patient and/or companion, with solid tumors and who had undergone at least one cycle of chemotherapy before data collection, as well as accepting to participate in the research, by signing the Free and Informed Consent Term (FICT).

The excluded patients were those submitted only to oral and/or subcutaneous and/or intramuscular chemotherapy, those without cognitive conditions, patients undergoing hematological treatment and, finally, those taking medications known to affect the immune system.

The elected patients were randomized into three groups with the following nomenclatures: control, ILIB 30' and ILIB 60', by means of a drawing carried out by a member of the nursing team, not involved in the data collection process. To encourage the participation of patients excluded from the follow-up, a new draw was carried out with the same indication of the procedure on a different card.

After the allocation of patients,

follow-up protocols were performed exclusively for each group. The variables characterizing the participants were: age (adults/elderly); sex (female/male); being under treatment with cytotoxic drugs for the hematopoietic tissue. [11]

In order to ensure that the participants were receiving the interventions uniformly, the Unit's Standard Operating Procedure (SOP) was followed for the application of the ILIB, which was carried out by trained nurses, so that the researchers did not participate in the subject. These professionals were supervised by a professional with expertise in laser therapy who checked the procedure with the SOP in the form of a checklist.

For the interventions, a low-intensity laser equipment was used, whose active medium is a semiconductor diode that emits 660 nm in wavelength, with an optical power of 100 mW and a beam cross-sectional area of 0.0434 cm^2, of the brand DMC do Brasil (THERAPY ILIB, DMC, São Carlos, Brazil). The duration of irradiation of the vascular bundle in the region of the radial artery was given at a different time for each intervention group.

Thus, the ILIB 30' and 60' transcutaneous application protocols were based on the ILIB Therapy recommended by the manufacturer. [12] Being in: Control Group (n = 21), did not receive laser therapy; ILIB 30' group (intervention group with n = 21): received the laser application for 30 minutes daily, for 10 consecutive days, except on Saturdays, Sundays and holidays. At the end of the first cycle, there was a 20-day break and the protocol was repeated. ILIB 60' group (intervention group with n = 13): in a period of 10 days, it received five laser applications for 60 minutes, with intervals of 48 hours between each application. During this period, there were interruptions on Saturdays, Sundays and holidays. At the end of the first cycle, there was a 20-day break and then the protocol was resumed.

For the primary outcome, the efficacy of transcutaneous ILIB applied for 30 and 60 minutes on adverse effects on hematopoietic tissue (thrombocytopenia, neutropenia and hemoglobin alterations) was considered and the effectiveness for intervention, when the patient maintained or increased the hematological parameters recommended by the Institution for the continuity of treatment in the three follow-up groups: Hemoglobin (≥ 9.0g/dl), Platelets (≥100,000/mm3), Neutrophils (≥ 1,500/mm3). This evaluation was carried out before the first session and after the last session foreseen by the SOP.

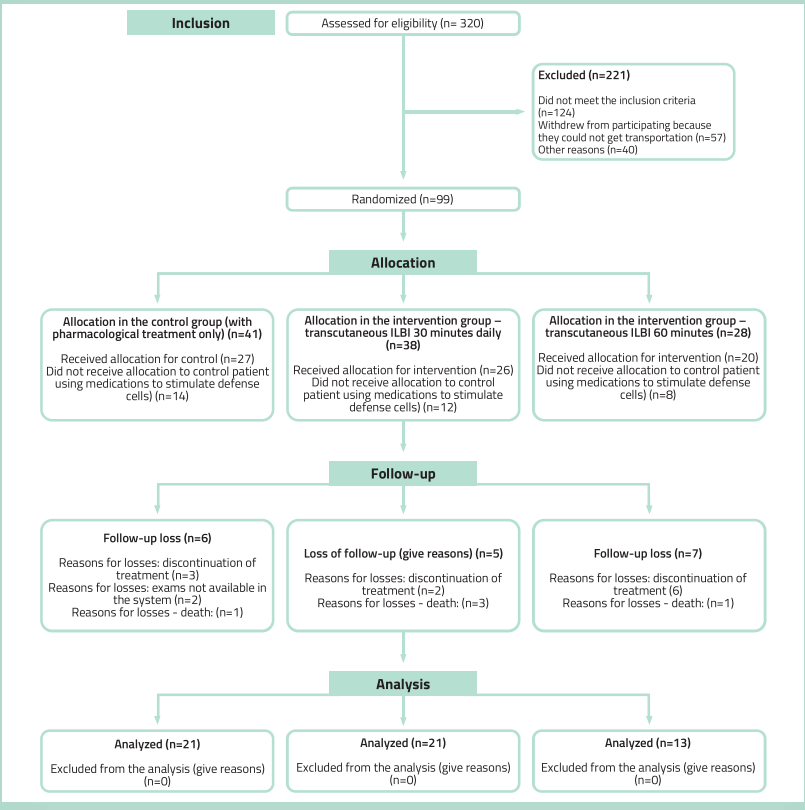
As a secondary outcome, it considered the adverse effects on skin integrity (site of application) of patients exposed to transcutaneous ILIB, mainly signs of burns, evaluated according to gradation. [13]

As it is a single-blind research, the results were only known by the researchers of this study, after the completion of data collection.

In case of non-compliance with protocols in the follow-up phase, the participants were excluded from the sample and replaced, according to the inclusion criteria (Figure 1).

Thus, 18 patients were lost to follow-up, six in the control group, five in the ILIB 30' intervention group and seven in the ILIB 60' group, among the reasons: discontinuation of treatment;

Figura 1. Fluxograma dos procedimentos de inclusão, alocação, seguimento e análise da amostra da pesquisa.



Source: Database organized by the researcher, 2019.

unavailability of laboratory tests in the electronic medical record, as well as death, as shown in Figure 1.

With the database in Excel Spreadsheet, the variables were analyzed descriptively, using the SAS Program for Windows, v. 9.4, and subjected to specific tests. With the variables categorized, chi-square trend tests were chosen, evaluating the occurrences in each group, at each moment.

With the quantitative variables, comparisons of means were carried out according to a factorial design to evaluate the group versus moments interaction, using a generalized linear model with Poison distribution, followed by Wald's multiple comparison test.

RESULTS

The analyzes showed homogeneity in the composition of the control groups and ILIB 30' and 60' interventions as they did not present statistically significant differences between the variables age (p=0.4134) and sex (p=0.9272). The final sample consisted of 55 patients: 21 allocated to the control group (mean age = 53.86; ± 14.24 years), 21 in the ILIB 30' intervention group (mean age = 57.81; ± 11.33 years) and 13 in the ILIB 60' intervention group (mean age = 52.85; ± 7.55 years).

All participants had solid tumors diagnosed and underwent at least one cycle of chemotherapy prior to data collection, specifically with cytotoxic drugs for hematopoietic tissue.

There was a favorable outcome for the effectiveness of transcutaneous ILIB in both protocols (ILIB 30' and 60'), in controlling side effects for the maintenance or increase of minimum parameters of blood components: hemoglobin (86%; 85%), platelets (100%; 100%), neutrophils (100%; 92%) (Tables 1 and 2).

Better efficacy was observed in the 30' ILIB protocol for platelet and neutrophil elevation, when compared to the 60' protocol (Chart 3).

Chart 1. Efficacy of the transcutaneous ILIB 30' protocol, with a wavelength of 660nm, on hematopoietic adverse effects (hemoglobin, platelets, neutrophils) of intravenous antineoplastic chemotherapy in outpatients aged 18 years and over. Public Hospital of the State of São Paulo, 2019

P.	Hemoglobin (≥ 9,0g/dl)			Platelets (≥ 100.000/mm3)			Neutrophils (≥ 1.500/mm3)		
	Before	After	Efficiency	Before	After	Efficiency	Before	After	Efficiency
1	10,6	8,8	NO	279.000	301.000	YES	3,68	8,55	YES
2	10,9	10,5	YES	138.000	301.000	YES	0,64	2,47	YES
3	9,7	8,4	NO	150.000	130.000	YES	3,35	3,23	YES
4	13,1	11,8	YES	168.000	222.000	YES	3,63	2,26	YES
5	12,6	12,5	YES	280.000	312.000	YES	3,18	5,46	YES
6	11,8	13,0	YES	281.000	250.000	YES	0,61	2,96	YES
7	13,3	13,4	YES	194.000	215.000	YES	3,86	1,70	YES
8	11,0	10,6	YES	99.000	130.000	YES	0,98	1,85	YES
9	11,7	11,7	YES	243.000	304.000	YES	1,34	3,84	YES
10	10,9	10,6	YES	179.000	133.000	YES	1,49	1,72	YES
11	13,8	12,6	YES	182.000	273.000	YES	3,65	4,84	YES
12	14,0	13,6	YES	138.000	138.000	YES	1,32	1,66	YES
13	12,5	12,5	YES	304.000	258.000	YES	2,21	4,41	YES
14	13,5	13,9	YES	306.000	423.000	YES	0,66	3,45	YES
15	12,1	11,0	YES	135.000	100.000	YES	1,07	1,42	NO
16	11,8	11,9	YES	338.000	391.000	YES	1,50	5,07	YES
17	9,0	7,1	NO	332.000	226.000	YES	3,44	2,25	YES
18	9,1	10,2	YES	233.000	244.000	YES	1,46	1,78	YES
19	11,9	12,1	YES	114.000	120.000	YES	3,36	2,76	YES
20	10,6	9,5	YES	161.000	142.000	YES	2,05	2,64	YES
21	11,4	12,9	YES	230.000	173.000	YES	2,13	1,58	YES
	Efficiency = 86%			Efficiency = 100%			Efficiency = 95%		

Source: Database organized by the researcher, 2019.

Efficacy: maintenance or increase of minimum parameters of blood components for continuity of chemotherapy treatment: Hemoglobin (≥ 9.0g/dl); Platelets (≥ 100,000/3); Neutrophils (≥ 1.500/mm3).

Chart 2. Efficacy of the transcutaneous ILIB 60' protocol, with a wavelength of 660nm, on the hematopoietic adverse effects of intravenous antineoplastic chemotherapy in outpatients, aged 18 years and over. Public Hospital of the State of São Paulo, 2019

P.	Hemoglobin (≥ 9,0g/dl)			Platelets (≥ 100.000/mm3)			Neutrophils (≥ 1.500/mm3)		
	Before	After	Efficiency	Before	After	Efficiency	Before	After	Efficiency
1	11,8	11,4	YES	549000	192000	YES	3,15	2,14	YES
2	12,1	13,6	YES	380000	287000	YES	2,16	3,18	YES
3	12,2	11,9	YES	241000	260000	YES	2,48	2,74	YES
4	11,7	12,7	YES	250000	262000	YES	2,28	2,32	YES
5	12,7	9,6	YES	263000	149000	YES	3,17	3,40	YES
6	13,2	11,6	YES	173000	180000	YES	1,87	1,30	NO
7	11,4	11,9	YES	435000	425000	YES	2,76	1,72	YES
8	9,2	10,2	YES	252000	231000	YES	8,35	5,02	YES
9	8,9	10,4	YES	204000	153000	YES	0,72	2,24	YES
10	11,9	6,9	NO	193000	224000	YES	1,72	1,85	YES
11	11,3	8,8	NO	537000	106000	YES	1,60	6,39	YES
12	11,8	12,5	YES	345000	262000	YES	1,39	2,17	YES
13	12,9	9,6	YES	176000	224000	YES	2,64	3,19	YES
	Efficiency = 85%			Efficiency = 100%			Efficiency = 92%		

Source: Database organized by the researcher, 2019.

Efficiency: maintenance or increase of minimum parameters of blood components for continuity of chemotherapy treatment: Hemoglobin (≥ 9.0g/dl); Platelets (≥ 100.000/mm3); Neutrophils (≥ 1.500/mm3).

Chart 3. Comparison of the efficacy of transcutaneous ILIB 30' and 60' protocols, with a wavelength of 660nm, on the hematopoietic adverse effects of intravenous antineoplastic chemotherapy in outpatients, aged 18 years and over. Public Hospital of the State of São Paulo, 2019

Variables	Groups	Moments				p-value
		Before		After		
		Mean	SD	Mean	SD	
Hemoglobin	Control	11,79aA	1,61	11,89aA	1,56	0,231(*)
	30' intervention	11,68aA	1,44	11,36aA	1,82	
	60' intervention	11,62aA	1,27	10,85aA	1,83	
Platelets	Control	271,67aA	87,66	241,17aA	62,2	0,1133(*)
	30' intervention	213,52aB	75,19	227,90aB	91,31	
	60' intervention	307,54aA	130,99	227,31bA	79,59	
Neutrophils	Control	3,81aA	2,31	3,09aA	1,33	0,0197(*)
	30' intervention	2,17aB	1,17	3,14bA	1,75	
	60' intervention	2,64aAB	1,86	2,9aA	1,42	

Source: Database organized by the researcher, 2019

(*) A generalized linear model with negative binomial distribution (specific for counting data with extra variation) was used to compare the means between the groups, evaluating the group versus moments interaction.

Means followed by a lowercase letter (fixing groups and comparing moments) do not differ at the 5% level

Means followed by a capital letter (fixing moments and comparing groups) do not differ at the 5% level.

Regarding patient safety, 1st degree burns were found in four patients, three of which resulted from the ILBI 30' protocol and one from the ILIB 60'. The four patients were classified as high phototype (black). Their main complaints were transient pain and sensation of heat at the application site, with signs of erythema or hyperpigmentation and dry skin.

The reduction in irradiation in the four patients partially compromised the treatment, once the transcutaneous ILIB therapy was 100% effective for the maintenance or elevation of platelets and neutrophils and a reduction from 85-86% to 50% for hemoglobin.

DISCUSSION

Efficacy of transcutaneous laser therapy with a wavelength of 660nm was confirmed through both ILIB 30' and 60' protocols, as an alternative treatment in maintaining or increasing minimum parameters of blood components of patients who are receiving chemotherapy. This effectiveness ranged from 85% to 100% and was limited to the type of blood component: hemoglobin (85%; 86%), platelets (100%; 100%) and neutrophils (95%; 92%), respectively to the ILIB 30' and 60' protocols.

The ILIB 30' protocol proved to be more effective in the production of platelets and neutrophils when compared to the ILIB 60', therefore, it is understood as the first choice; however, the ILIB 60' protocol may be an alternative, especially for outpatients.

The result is an unprecedented outcome, since only one Russian study, carried out in 2012, was found by literature review, demonstrating a reduction in leukopenia in breast cancer patients undergoing chemotherapy; however the focus of the study was on intravenous ILIB therapy [14] and not transcutaneously, as proposed in this study.

Thus, the data proved to be favorable for the adoption of the use of transcutaneous ILIB as a prevention or alternative treatment for anemia, neutropenia and/or thrombocytopenia in patients undergoing antineoplastic chemotherapy, including the possibility of replacing drug or transfusion therapies.

Most patients (93.3%) undergoing antineoplastic chemotherapy have a drop in at least one of the elements in the red blood count series. In the red series, 73.3% suffer from a drop in the number of red blood cells and 66.7% in the levels of hemoglobin and hematocrit. As for the platelet series, 53.3% showed thrombocytopenia. [15]

Furthermore, neutropenia has influenced the high mortality rate of hospitalized cancer patients (80%) [16], because it is a reduction in the number of granulocytes in the blood, an individual's defense element, making the patient susceptible to serious bacterial and fungal infections. [17]

Regarding patient safety regarding the ILIB 30' and 60' protocols, there was a need for the device manufacturer to develop a new protection device for high phototype (black) people. The high phototype, according to Fitzpatrick, is the phototype that always tans and burns little, with this, it can be concluded that the dose of light used for low phototypes can be higher than for higher phototypes. By following this classification, burn hazards can be minimized and even eliminated. [18]

Exclusively, these patients had 1st degree burns (12%). Fortunately, the extender provided by the manufacturer, in order to increase the distance between the light source and the patient's skin, was not sufficient to protect the skin, it was necessary to adapt opaque tape in order to reduce irradiance by 25%, care that protected the most susceptible patients without reducing the effectiveness of therapy for platelets and neutrophils; however, there was a reduction of 35 to 36% for the hemoglobin parameter.

The main complaints of patients who suffered burns involved: transient pain and sensation of heat at the application site, according to the operators' observations, associated with erythema or hyperpigmentation, as well as skin dryness. These findings corroborate those raised by an integrative review on adverse events resulting from aesthetic care in the use of laser therapy. [19]

Therefore, prior knowledge about the characteristics of the treated patient's phototype is also necessary to prevent adverse events and promote safety. However, the fact that such an event occurred may be associated with the low scientific production in relation to the transcutaneous ILIB.

Despite the autonomy attributed to the nurse to operate the low power laser, the need for professionals to constantly base their practice on new scientific evidence in the area is highlighted, in order to ensure the implementation of laser therapy as a nursing intervention in health services.

During the execution of this research, limitations were encountered: difficulty in allocating and completing the follow-up of patients undergoing outpatient chemotherapy treatment due to difficulties in moving from the cities of origin to the treatment center, since there was little initial adherence to treatment and non-adherence to protocols due to the difficulty of understanding the patient about the safety of a little-known treatment.

CONCLUSION

The study estimated 85% to 100% efficacy of transcutaneous laser therapy for both protocols (ILIB 30' and 60'), and may be recommended as an alternative treatment in the maintenance or increase of minimum parameters of blood components (hemoglobin, platelets and neutrophils) in patients undergoing antineoplastic chemotherapy.

Considering that the ILIB 30' protocol proved to be more effective in the production of platelets and neutrophils when compared to the ILIB 60', the 30' protocol is recommended as the first choice; however, due to the limitation of the outpatient to attend daily for the applications, the ILIB 60' protocol may be an alternative, due to its proven effectiveness.

In view of the adverse effects related to first-degree burns, with 12% of patients affected and exclusively high phototype (black skin), it is recommended to the manufacturer of the ILIB device used in the protocols, improve the extender coupled to the light source, in order to reduce the irradiance of the device by 25%.

The scientific evidence produced by this research relevant to the effectiveness of low-level transcutaneous laser therapy proposes to establish as a nursing procedure, the ILIB 30' and 60' protocols in chemotherapy units, through Standard Operating Procedures for adult and elderly patients, with nurses duly trained to administer the treatments.

Finally, further research is suggested to deepen the impact of transcutaneous ILIB on patients' quality of life, the effectiveness of the procedure through biochemical changes and cancer pain control, as well as finding the best dosimetry for application.

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