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REVIEW

Brazilian blood donation eligibility criteria for dermatologic patients *

Critérios brasileiros de elegibilidade à doação de sangue para pacientes dermatológicos

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Abstract: A focused and commented review on the impact of dermatologic diseases and interventions in the solidary act of donating blood is presented to dermatologists to better advise their patients. This is a review of current Brazilian technical regulations on hemotherapeutic procedures as determined by Ministerial Directive #1353/2011 by the Ministry of Health and current internal regulations of the Hemotherapy Center of Ribeirão Preto, a regional reference center in hemotherapeutic procedures. Criteria for permanent inaptitude: autoimmune diseases (>1 organ involved), personal history of cancer other than basal cell carcinoma, severe atopic dermatitis or psoriasis, pemphigus foliaceus, porphyrias, filariasis, leprosy, extra pulmonary tuberculosis or paracoccidioidomycosis, and previous use of etretinate. Drugs that impose temporary ineligibility: other systemic retinoids, systemic corticosteroids, 5-alpha-reductase inhibitors, vaccines, methotrexate, beta-blockers, minoxidil, anti-epileptic, and anti-psychotic drugs. Other conditions that impose temporary ineligibility: occupational accident with biologic material, piercing, tattoo, sexually transmitted diseases, herpes, and bacterial infections, among others. Discussion: Thalidomide is currently missing in the teratogenic drugs list. Although finasteride was previously considered a drug that imposed permanent inaptitude, according to its short half-life current restriction of 1 month is still too long. Dermatologists should be able to advise their patients about proper timing to donate blood, and discuss the impact of drug withdrawal on treatment outcomes and to respect the designated washout periods.
Keywords: Blood banks; Blood transfusion; Teratogenic dangers

Resumo: Uma revisão centrada no impacto de doenças e intervenções dermatológicas no ato solidário de doar sangue é apresentada aos dermatologistas para melhor aconselhamento dos seus pacientes. Esta é uma revisão das atuais normas técnicas brasileiras sobre procedimentos hemoterápicos conforme determinado pela Portaria Ministerial no 1353/2011 do Ministério da Saúde e atuais normas internas do Hemocentro de Ribeirão Preto, um centro de referência regional em procedimentos hemoterápicos. Critérios para inaptidão definitiva: doenças autoimunes (>1 órgão comprometido), antecedente pessoal de câncer diferente de carcinoma basocelular, dermatite atópica ou psoríase graves, pênfigo foliáceo, porfirias, filariose, hanseníase, tuberculose ou paracoccidioidomicose extrapulmonares e uso prévio de etretinato. São condições de inelegibilidade temporária: uso de outros retinóides sistêmicos, corticoides sistêmicos, inibidores da 5-alfa-redutase, vacinas, metotrexato, betabloqueadores, minoxidil, anticonvulsivantes e antipsicóticos. Outras condições responsáveis por inaptidão temporária: acidente ocupacional com material biológico, "piercing", tatuagem, doenças sexualmente transmissíveis, herpes, infecções bacterianas, entre outras. Discussão: Talidomida atualmente não consta na lista de medicações teratogênicas. Apesar do uso da finasterida já ter sido considerada como critério para inaptidão definitiva, de acordo com sua meia-vida curta a restrição atual de 1 mês ainda é demasiadamente longa. Dermatologistas devem ser capazes de aconselhar seus pacientes sobre o momento adequado para doar sangue e discutir o impacto da suspensão de medicações nos resultados do tratamento de forma a respeitar os períodos de restrição designados.
Palavras-chave: Bancos de sangue; Perigos teratogênicos; Transfusão de sangue

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INTRODUCTION

Dermatologic diseases and interventions can potentially interfere with aptitude to blood donation. Brazilian technical regulations on hemotherapeutic procedures are currently based on the Ministerial Directive #1353/2011 by the Ministry of Health (MS), which is valid for Brazilian territory and has recently substituted the Resolution RDC #153/2004 by the National Sanitary Surveillance Agency (ANVISA). [1,2] The adoption of regulations is required for safety and quality assurance of blood samples and its components. Such regulation determines that all blood donors must sign an informed consent form, declaring to donate the blood for whoever may require and that the donated material will be submitted to laboratory tests required by current law and technical regulations. Before blood donation, the candidate undergoes an interview with a trained health professional of tertiary degree in a private and confidential environment to evaluate past medical history and current health status to secure donation safety for both the recipient and the donor.[1]

During the course of this interview some dermatologic conditions or drugs might determine eligibility. The volunteer may de dismissed due to prohibitions and restrictions that can be temporary or permanent. [1] This review provides a reference guide to aid dermatologists to better advise their patients on the impact of the treatments and conditions in blood donation by reviewing national regulations by the Ministerial Directive #1353/2011, and local, more strict, internal regulations from the Regional Center for Hemotherapy – Hospital of Clinics of Ribeirão Preto – Faculty of Medicine of Ribeirão Preto – University of São Paulo (Hemotherapy Center of Ribeirão Preto).

ELIGIBILITY CRITERIA

According to the current regulations volunteers may donate blood if the criteria to safeguard donor or recipient safety are fulfilled. Individuals must be at least 18 years old and must not have completed 68 years of age. Sixteen and 17 year-old volunteers are allowed to donate blood if a signed informed consent is provided by a responsible adult. Minimal body weight is 50kg. For whole blood donations male donors must respect a minimum interval of two months between donations and may donate up to four times a year. Female donors may donate up to three times a year, with a minimum interval between donations of three months. The minimal interval for donation of plasma and platelets by apheresis is 48 hours, and shall not exceed four donations in the period of two months and one month respectively, or 12 and 24 donations in a year, respectively. [1] Dermatologic conditions and drugs may restrict blood donation according to the data presented on tables 1-3. Since it is unpractical to list all dermatologic diseases, current regulations may serve as a guideline for case-by-case decision for aptitude.

BENEFITS CONFLICT WITH BLOOD DONATION: HEMOCHROMATOSIS, POLYCYTHEMIA VERA, AND PORPHYRIA CUTANEA TARDA (PCT)

Patients with porphyrias, including PCT, are currently permanently ineligible for blood donation. [1] PCT is the most frequent of porphyrias, and although it can be triggered by viral infections such as Hepatitis C, B, and HIV, many patients are negatively screened and many patients present high serum iron, iron saturation and ferritin levels, resembling patients with hemochromatosis. Patients with polycythemia vera may present dermatologic symptoms such as aquagenic pruritus. [3-12] Although these patients may seem to be perfect candidates to donate blood from therapeutic phlebotomy sessions, they fail to qualify as blood donors. One of the principles of blood donation is that volunteers must not present direct or indirect benefits. [1] Thus, phlebotomy is considered a treatment with benefits to the donor, which may compromise interview reliability and recipient safety, by a risk of a less truthful acknowledgement of risk behaviors during the interview. In the United States, FDA does not prohibit the use of blood from therapeutic bleedings, but requires that blood intended for transfusion be labeled with the donor's disease. [13] This requirement is considered to be a barrier to the use of blood for transfusion. Providing therapeutic phlebotomy free of charge, even if the donor is ineligible as an allogenic blood donor, is a form of increasing interview reliability from such donors. Therefore, if properly requested, the FDA may allow omitting labeling for blood from hereditary hemochromatosis donors if the establishment clearly states in the informed consent for donation that they provide therapeutic phlebotomy free of charge. [13]

INCREASED INFECTION RISK: BODY PIERCING, TATTOO, OCCUPATIONAL BIOLOGIC ACCIDENT, SEXUALLY TRANSMITTED DISEASES, AND SEXUAL BEHAVIOR

Individuals must wait six months to be eligible to donate blood if piercing or tattoo were performed under safe sanitary conditions (sterile or disposable equipment). Otherwise, they are deferred for one year. [1] This period also applies to individuals who have suffered occupational biologic accident or acquired and treated sexually transmitted diseases such as gonorrhea, syphilis. [1] Keeping a piercing in any muco-

Table 1: Inaptitude period to blood donation by dermatologic diseases according to the Ministerial Directive #1353/2011, Ministry of Health, Brazil

Inaptitude time	Disease / Condition
Permanent	Autoimmune diseases (>1 organ involved) Atopic dermatitis (severe) Filariasis Leprosy Paracoccidioidomycosis (systemic) Personal history of cancer Pemphigus foliaceus Porphyrias Psoriasis, severe Squamous Cell Carcinoma (invasive) Tuberculosis (extra pulmonary)
5 years	Paracoccidioidomycosis (pulmonary) Tuberculosis (pulmonary)
12 months	Occupational accident with infective material Piercing or Tattoo (unknown sanitary conditions or in mucosa). Sexually Transmitted Diseases
6 months	Dengue (hemorrhagic form) Erythema Multiforme Erythroderma Herpes zoster Lichen planus Piercing or Tattoo (sterile/disposable equipment)
3 months	Plastic Surgery (local anesthesia)
4 weeks	Dengue
3 weeks	Chickenpox
2 weeks	Bacterial infections, uncomplicated Rubella
During course / healing	Allergic reactions (dermatitis or urticaria) Herpes Simplex (including genital) Small procedures (e.g. removal of warts and nail) Skin lesions at the site of venipuncture
After evaluation	Lymphadenopathy
None	Basal Cell Carcinoma or in situ Squamous Cell Carcinoma

sa or experiencing sexual activity with increased infection risks such as male homosexual intercourse, sexual promiscuity, and prostitution will cause a deferral of one year since the last exposure[1]. The volunteer is considered unsafe and therefore is temporarily ineligible to donate blood. Individuals with low infection risk are deferred for six months, while those with higher infection risks must wait for a full year. Other situations with increased infection risks such as nail beauty care in manicure or pedicure saloons with unsafe sanitary conditions, such as shared supplies are unlisted. Although those with genital herpes simplex are allowed to donate blood after the healing period of the lesions, in case of primary infection it could be considered criteria of sexually transmitted disease. [1]

RISK OF OCCULT DISEASE: LICHEN PLANUS AND HERPES ZOSTER

Lichen planus and herpes zoster are formal contraindications to blood donation. After complete cure, patients are allowed to donate blood only after six months. Lichen planus may be associated with viral infections such as hepatitis C. [14] Herpes zoster may be associated with malignancy and HIV infection. [15] As primary herpes zoster virus infection (chickenpox) is usually unrelated to immunodeficiency, individuals may donate blood after three weeks of its cure. [1]

AUTOIMMUNE DISEASES: ALOPECIA AREATA, CUTANEOUS LUPUS ERYTHEMATOSUS, PEMPHIGUS, AND VITILIGO

Patients with pemphigus foliaceus or autoimmunity involving more than one organ are currently ineligible for blood donation. [1] Dermatologic diseases such as alopecia areata, cutaneous lupus erythematosus, and vitiligo fit into the category of skin autoimmune diseases with no more than one organ involved (skin) and thereby may suffer no restrictions.

Although memory lymphocytes may be contaminants in the transfusion components, in the lack of evidence of transmission of such diseases by blood donation, current legislation prohibits blood donation from people with severe or multi-organ involvement. Pemphigus vulgaris patients may be considered permanently inapt to donate by following the pemphigus foliaceus criteria.

PSORIASIS

Severe forms of psoriasis, including extensive cutaneous involvement cause permanent inaptitude to donate blood. [1] Patients with mild forms of psoriasis, without arthritis, are allowed to donate, provided they are not using prohibitive drugs. [1] It is curious that individuals that presented erythroderma are only deferred for six months, since exacerbation of underlying skin disease such as psoriasis is frequently its cause.

LEPROSY

Patients with personal history of leprosy are currently forbidden to donate blood despite treatment and cure, in comparison with patients with previous history of pulmonary tuberculosis, who can donate blood 5 years after the cure. [1] Brazil is endemic for leprosy and the population is frequently exposed to the bacilli. Foss et al.[16] detected almost 3% positivity (10/324) by ELISA Anti-PGL1 (IgM) in healthy blood donors from the Hemotherapy Center of Ribeirão Preto. Although all 10 healthy donors turned out to be leprosy free during screening and follow-up, the frequency of positive serologic test was higher than in 21 patients with tuberculoid or borderline leprosy from the same study (0/16 patients with tuberculoid leprosy and 0/5 patients with borderline leprosy). It is prudent to prohibit blood donation from patients who have been treated for leprosy, because of increased individual susceptibility and possible reinfection. It would be proper to include leprosy household contacts in the same list.

TERATOGENIC DRUGS

Dermatologists are the only physicians who prescribe all of the teratogenic drugs listed on table 2. Neither methotrexate nor thalidomide use have been cited in the current national hemotherapy regulations as cause of inaptitude to blood donations, in spite of well-known teratogenic effects. The Brazilian ministry of health further advises prohibitive measures for breast-feeding and blood donation for thalidomide, but it is absent in this ministry directive. [17] While leprosy currently imposes permanent inaptitude for donation in cases of erythema nodosum leprosum, thalidomide could also be indicated (off-label) for severe prurigo nodularis, neutrophilic dermatoses, and cutaneous lupus erythematosus. [18]

RETINOIDS

Isotretinoin users must abstain from blood donations for at least 1 month.[1] Those who have ever taken etretinate are permanently ineligible for blood donations. [1] Previously, acitretin use was a cause of permanent inaptitude, but since 2011 people who have taken acitretin can donate after a washout period of 3 years. [1, 2] Acitretin is a second-generation retinoid that has substituted etretinate in the treatment of psoriasis and diseases of keratinization. Although acitretin presents reduced half-life, re-esterification to etretinate is possible (reverse metabolism) by ethanol ingestion and etretinate has extremely long elimination period because of accumulation in adipose tissue. [19-22] Blood donation criteria seem to follow the recommendations for anti-conception for female users, however topical retinoids are unmentioned.

Table 2: Dermatological drugs and vaccines that preclude blood donation according to the Ministerial Directive #1353/2011, Ministry of Health, Brazil

Reason	Inaptitude time	Drug
Teratogenicity*	Permanent	Etretinate
	3 years	Acitretin
	6 months	Dutasteride
	1 month	Finasteride
		Isotretinoin
Other	4 weeks	Vaccines (attenuated microorganisms)**
	1 week	Antipsychotic drugs (Pimozide)
	2 days	Beta blockers
		Corticosteroids, Systemic***
		Minoxidil
		Vaccines (toxoids/ inactivated microorganisms)
	During use	Antibiotics
		Anti-epileptic drugs (Carbamazepine)
	None	Calcium-channel blockers
		Diuretics
Platelet Concentrate****	5 days	NSAIDs

*Drugs methotrexate and thalidomide are unlisted. ** Includes Bacillus Calmette-Guérin intradermal vaccine. *** Although topical steroids are not a contraindication to blood donation, the disease might be **** Inaptitude time for platelet concentrate donation only.

5-α-REDUCTASE INHIBITORS

Finasteride users must not donate blood for at least 1 month since the last dosage and dutasteride users must abstain from blood donations for at least 6 months. [1] Past regulatory resolution RDC #343/2002 was even more prohibitive for finasteride users. [23] Finasteride use was carried out as a permanent impediment to blood donation, which probably resulted in loss of blood donors during the 18 months it was valid.

Because finasteride has a short half-life (2-12 hours, Table 3) the washout period could be even shorter, such as one week, especially with a low dosage of 1 mg per day. Dutasteride, on the other hand, presents a long half-life of 5 weeks (Table 3), and demands a longer washout period. [24] It is questionable if patients with male-pattern alopecia or benign prostatic hyperplasia would sacrifice treatment for more than one month to donate blood. Balding patients would hardly endure long period only to donate blood if taking dutasteride. For these blood donors finasteride or topical products would be more appropriate options.

Labeling changes could be implemented on hemotherapy derivatives from patients taking teratogenic drugs to prevent them from being transfused to pregnant women.

SURGERY

Volunteers who have undergone surgery are temporarily deferred according to the type of surgery and clinical evolution. If performed under local anesthesia, plastic surgery patients are deferred for three months (Table 1). If it is performed under general, epidural or spinal anesthesia, the deferral time is six months. [1] Individuals may donate after healing period after removal of warts, nails, and other minor dermatological procedures. [1] In the case of elective surgery actions to reduce the consumption of allogeneic hemocomponents must be considered, such as methods to reduce intraoperative bleeding or planning for autologous transfusion, which must be performed at least three days prior to the surgery. [1]

COSMETIC TREATMENTS

Current national regulations do not advise about the use of injectable cosmetic products. However, the internal directives of the Regional Center of Hemotherapy, which are more prohibitive, list a 1-month restriction since the last injection of botulinum toxin A, regardless of therapeutic or cosmetic use. There are no specific restrictions for fillers or non-injectable cosmetic treatments, such as LASER treatments and chemical peels.

The unlisted cosmetic treatments are managed on a case-by-case decision, most probably as minor surgical treatment, prohibited during healing and inflammation period.

AUTOLOGOUS BLOOD TRANSFUSION

As it imposes no interpersonal transmission, the impediment criteria are less strict. It can only be performed if requested by the patient´s physician and approved by the hemotherapist in charge. Although the blood samples are submitted to the same tests, even patients with chronic viral infections are eligible

Table 3: Drugs prescribed by dermatologists that may cause blood donation ineligibility. Half-lives and current inaptitude times are presented

Drug Class	Drug	Half-Life*	Inaptitude Time
Retinoids	Etretinate	120 days (84-168 days)	Permanent
	Acitretin	49 hours**	3 years
	Isotretinoin	21 hours	1 month
5-α-Reductase Inhibitors	Dutasteride	5 weeks	6 months
	Finasteride	6 hours (2-16 hours)	1 month
Other	Methotrexate	3-10 hours	1 month***
	Thalidomide	5-7 hours	N/A
	Pimozide	55 hours	1 week
	Minoxidil	3.5-4.2 hours	2 days
	Propranolol	3-6 hours	2 days
	Prednisone	~3.5 hours	2 days

*Based on Lexi-Drugs (Smartphone/PDA Software for Physicians) Lexicomp © 2010 Lexi-Comp Inc. Hudson, OH. **Active reverse-metabolite of acitretin is etretinate. ***Methotrexate is listed in the internal regulations of Hemotherapy Center of Ribeirão Preto.

for autologous blood donation. [1] For example, a patient with psoriasis taking methotrexate is scheduled to have an elective surgery, which could result in severe blood loss. According to internal regulations of the hemotherapy center, the patient must be off of methotrexate for 30 days before being eligible to donate for the general population (Table 3). This requirement about methotrexate is waived since the blood will be given back to the same patient with autologous blood donation.

FINAL COMMENTS

Although it is the hemotherapist´s role to decide if a volunteer meets the suitability requirements for the solidary act of donating blood, it is the dermatologists' role to provide information for their patients about proper medication withdrawal and timing to donate blood and discuss implications for treatment outcomes. Dermatologists should also warn patients with a dermatologic diagnosis that carries a risk of occult disease to restrain from donating blood for at least six months after complete cure, as patients may forget the diagnosis after cure, making a presumptive diagnosis impossible by the hemotherapist. Thus, dermatologists can contribute to the safety of blood transfusions. ❑

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