Review Article

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De Novo Cancer And Lymphoproliferative Disorders After Liver Transplantation

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1. Abstract

While the long-term survival outcomes following liver transplantation (LT) have improved significantly during the last decade, de novo malignancies (DNM´s) remains a major cause of patient late mortality. Nonmelanoma skin cancer is the most common malignancy (37% of total), with a near 10-fold greater risk than the in an age-matched and sex-matched general population, but no impact on patient survival. It is followed by posttransplant lymphoproliferative disorder (PTLD) specially in pediatric LT recipients (25% of total), and other solid organ tumors such as lung, head and neck, and colorectal cancer, which are nearly 3-times more frequency in LT recipients than in an age-matched and sex-matched population (48% of DNM´s), and with significant impact on long term patient survival. The most important risk factors for posttransplant malignancy includes immunosuppression, chronic viral infections including Epstein-Barr virus associated posttransplant lymphoproliferative disease, sun exposure (for skin cancer), smoking, etiology of liver disease (especially alcoholic liver disease and primary sclerosing cholangitis), and biodemographic characteristics of receptors (specially increasing age, body weight, lifestyle factors and ethnicity/race). The increased incidence of DNM´s in LT recipients demands minimizing immunosuppressant usage, stratify recipients at higher risk and implement a careful and cost-effective long-term screening protocol to help facilitate diagnosis at an earlier stage of disease to offer favorable outcomes for LT recipients.

2. Keywords: De novo malignancies, liver Transplantation, incidence; posttransplant lymphoproliferative disorder; Skin cancer; Solid organ tumors; Surveillance.

3. Abbreviations: DNM´s: De novo malignancies; LT: Liver transplantation; IS: immunosuppression; SIR: Standardized incidence ratio; PTLD: posttransplant lymphoproliferative disorder

4. Introduction And Risk Factors

Over the last 30 years, liver transplantation (LT), has become the standard of care for patients with life-threatening liver diseases whether acute or chronic [1]. In 2023, approximately 41,000 LT were performed worldwide, with an increase of nearly 9.5% vs 2022, but only satisfying 10% of global needs [2] Due to advancements in LT techniques, postoperative management, newer immunosuppressive agents, perfusion machines, better selection of patients and critical care management, long-term survival after LT has markedly improved [1]. The current estimated 1-, 5-, and 10-year survival rates of LT patients is approximately 90%, 80%, and 75%, respectively in most transplant centers around the world [1, 3].

However, long-term LT survivors undergoing long-time immunosuppression (IS) face concerns about the significantly higher potential risk of De novo malignancies (DNM´s) when compared with the general population, due to the direct oncogenicity of IS and susceptibility to viral infections among other factors [4-6]. DNM´s, is one of the leading causes of late mortality after liver and kidney transplantation and accounts for more than 20% of deaths during long-term follow-up [7].

The development of cancer in LT recipients is multifactorial. IS agents activate directly cell-intrinsic tumorigenic pathways, impairs the ability of the host immune system to control viral oncogenic infections and reduces the tumor immunosurveillance, allowing cancer cells to proliferate without control [4, 8-14]. The main factors increasing the risk of DNM´s are the level of IS, the number of episodes of acute rejection, patient´s demographics (age, gender, race, etc.), the initial cause for LT, potential oncogenic viruses (Epstein-Barr virus [EBV], cytomegalovirus [CMV], human herpesvirus 8, hepatitis B and C viruses), the patient's behavior (smoking and alcohol abuse) and pre-existing premalignant conditions [4, 8, 9].

5. Incidence And Epidemiology Of De Novo Neoplasia Post LT

The overall incidence of DNM´s in LT recipients reported from single-center and registry studies, ranges from 10-14.5% at 5 years, to 20-32% at 10 years of LT [6,15]. LT recipients carry a 2-3-fold increased risk of solid organ malignancies and a 30-fold increased risk of hematologic and skin cancers, when compared with age- and sex-matched healthy controls from the general population

(standardized incidence ratio; SIR i.e., observed/expected cases) [8,15].

DNM´s have to be distinguished from recurrent cancers (0.3-22% of cancers in the post-LT patient) and from donor-derived cancers present in the transplanted organ (< 0.1%). Malignancies developing within the first 6 month of LT may have pre-existed and are thus not considered DNM´s, except for post-transplant lymphoproliferative disorders (PTLD´s) [16-18].

DNM´s are known to increase in frequency after the first year of LT, and peaks at 6-10 years of follow-up, thus the need to screen for DNM´s as part of the management of the post-LT patients [19, 20].

When considering only adult LT recipients, an extensive review of the literature including 16 published studies between 1997 and 2020, with more than 1,000 LT recipients each study, they showed that between 1-16.3% of patients transplanted developed DNM´s, depending on the follow-up and demographics of patients [9, 15] (Table 1).

Table 1. Estimated standardized incidence ratios for De novo malignancies after LT. (Adapted from ref 9)

Cancer Site/Type	Estimated incidence (%)	SIR
All cancers	6 May	1.9- 3
Kaposi´s sarcoma	0.14-2.8	> 100
Skin (non melanoma)	0.9-3.2	> 30
PTLD	0.9-2.6	20 Jun
Lip/oropharyngeal / head/neck	0.1-2	14 May
Esophagus	0.5 -1.19	12-18.7
Colorectal overall	0 – 0.65	1.41
Colorectal in IBD/ PSC	0.7-7.9	5 Mar
Stomach	0.25	3
Vulva	0.25	8 -23.8
Lung	0.6-1.2	8 Feb
Renal	0.35	2 - 2.6
Thyroid	0.2	4.6
Prostate	0.25-0.6	1
Breast	0.4	1
Colorectal in non-IBB/PSC	0.3	1

Abbreviations: IBD: Inflammatory bowel disease; PSC: Primary sclerosing cholangitis; PTLD: Posttransplant lymphoproliferative disease; SIR: Standardized incidence ratio=1 (risk not increased).

In the retrospective study of the French national registry, the incidence of solid organ de novo malignancies (excluding nonmelanoma skin cancers) in all LT patients performed between 1993 and 2012 was compared with that of the French population, standardized on age, sex, and calendar period. Among the 11,226 LT patients included in the study (mean age 50 years, 63% men, mean follow-up of 6,1 +/- 4,3 years), 1,200 DNM´s were diagnosed (10.7% of LT) (21). The SIR, for all de novo solid organ malignancies was 2.20 (95% CI 2.08-2.33), with higher risks in men (SIR 2.2) and LT for alcoholic liver disease (SIR 2.8).The risk of death was approximately 2 times higher in patients with DNM´s vs in those without DNM´s (48.8% versus 24.3%). The cancers with the highest excess risk were laryngeal (SIR = 7.5; 95% CI, 5.97-9.48), esophageal (SIR = 4.7; 95% CI, 3.56-6.24), lung (SIR = 2.5; 95% CI, 2.21-2.95), and lip-mouth-pharynx (SIR = 2.2; 95% CI, 1.72-2.77) [21].

In a more recent analysis of the French registry, with 11,004 adult LT performed between 2000 and 2013, with no history of pre-LT malignancy, except primary liver tumor, DNM´s was reported in 1,480 L T recipients (13.45%). The probability to develop a DNM´s after LT was 2.07% at 1 year, 13.30% at 5 years, and 28.01% at 10 years [22]. Of the known reported malignancies, the most common malignancies were hematological malignancy (22.36%), non-melanoma skin cancer (19.53%) and lung cancer (12.36%). With a competing risk regression multivariate analysis, there were significant risk factors for post-LT de novo malignancy including: recipient age (Subdistribution Hazard Ratio (SHR) = 1.03 95%CI 1.03-1.04), male gender (SHR = 1.45 95%CI 1.27-1.67), non-living donor (SHR = 1.67 95%CI 1.14-2.38), a first LT (SHR = 1.35 95%CI 1.09-1.69) and the type of initial liver disease (alcohol-related liver disease (SHR = 1.63 95%CI 1.22-2.17), primary sclerosing cholangitis (SHR = 1.98 95%CI 1.34-2.91), and primary liver tumor (SHR = 1.88 95%CI 1.41-2.54). The Initial ISA had no significant impact on DNM´s [22].

In the US Scientific Registry of Transplant Recipients database comprising 108,412 LT recipients performed between 1987 and March 2015 mean age 51.9 ± 10.8 years, 64.6% male, 74.5% white, and 15.8% with previous malignancy), and with a median follow-up of 6.95 years; the potential risk factors for malignancies after LT were assessed using Cox regression analysis for the outcome of time to first malignancy [23]. DNM´s during follow-up were 4,483(41.3%) skin cancers, 1,519 (14.0%) hematologic, and 4,842 (44.7%) solid organs. The 10-year probability of de novo malignancy was 11.5% (11.3-11.8%). On a multivariable analysis: age by decade (hazard ratio [HR], 1.52; $P < 0.001$), male sex (HR, 1.28; $P < 0.001$), white race (compared with other races: HR, 1.45-2.04; $P < 0.001$), multiorgan transplant (HR, 1.35; $P < 0.001$), previous malignancy (HR, 1.34; $P < 0.001$), and alcoholic liver disease, autoimmune, nonalcoholic steatohepatitis (HR, 1.35; $P < 0.001$), and primary sclerosing cholangitis pre-LT (compared with hepatitis C virus, $P < 0.001$) were associated with higher risk of post-LT malignancy. The type of IS was also not related to increase in DNM´s (P = NS) [23].

6. De Novo Neoplasia By Type

a) Skin cancers:

These are the most common DNM´s seen in adult LT recipients, accounting for almost 40% of malignancies in LT patients, although they generally do not impact patient survival. The most reported skin cancers includes: cutaneous squamous cell carcinoma (SCC),

basal cell carcinoma (BCC), melanoma, and Kaposi's sarcoma, depending on the age, sun exposure history and previous use of sun protection, and skin surveillance protocol implemented [8, 24]. The management of skin cancers requires a multidisciplinary approach with close communication between the transplant team and dermatologists, and sometimes including other specialists (surgeons, medical oncologists and radiation oncologists).

SCC is the most common skin cancer in post-LT patients, with a ratio of 2.4:1 vs BCC, occurring more commonly in sun exposed areas (75%) and being more aggressive than in the nontransplant population, with a risk for metastasis up to 8% vs 0,5%-5% in the general population [25].

Kaposi Sarcoma may present in 3% of LT patients with a SIR of 60. It is related with the oncogenic HHV8 infection. The seroprevalence of HHV8 is variable around the world with less than 5-10% in North and South America. The clinical course is variable, but many lesions will regress upon discontinuation of IS. The presence of visceral lesions affects negatively patient survival [26].

Melanoma has a SIR of 2-6 fold in LT patients [27]. The prognosis depends of depth of invasion (Breslow stage) and clinical staging at diagnosis. Management includes simple excision followed by widening of margins depending on Breslow depth and, where necessary, lymph node biopsy. The worse the prognosis, the more aggressive the approach. IS should be reduced and considered to switching to another drug with antiproliferative and antiangiogenic activity to reduce the risk of tumor spread (mTOR) [27]. In melanoma stage Ia or Ib, IS should be decreased mildly, and in Stage IV unresectable with metastatic melanoma, IS should be severely decreased or discontinued, and if no BRAF mutations, consider the use of immune checkpoint inhibitors.

b) PTLD:

PTLD is also frequent and a major and potentially life-threatening complication after solid-organ transplantation [8]. It is characterized by an uncontrolled lymphoproliferative state derived from B-cell lymphocytes (85%) o T-cells (15%) [28]. Although its pathogenesis is not completely understood, it is considered secondary to an intense IS post LT (especially with use of OKT3 or other antilymphocyte antibodies like ATG); where EBV plays a critical role, as demonstrated by the fact that > 80% of B-cell PTLD and 30% of T-Cell PTLD cases are associated with EBV (more common in pediatric patients [28].

The spectrum of PTLD is heterogeneous and range from reactive, polyclonal hyperplasia to high grade monoclonal lymphoma. The overall incidence of PTLD ranges from 1%–3% in adults to 6%–10% in pediatric series, with a SIR of 3.9–21 [28].

We have recently published a cohort study of 4 transplant centers from Latin America (Argentina, Brazil and Chile), with 28 patients developing PTLD out of 1,621 adult LT recipients (1,7%) after a mean follow-up of 39 months [29]. The mean age at diagnosis was 53.7 (± 14) yr with a mean time of 39.7 (± 35.2) months from LT to PTLD. PTLD location was frequently extranodal (80.7%) and mostly involving the transplanted liver (59.3%). Initial therapy included reduction in IS alone in 23.1% of patients, with either rituximab or chemotherapy as initial or second-line therapy in 76.9% of the patients. The overall survival at 1 and 5 yr post-PTLD diagnosis was 53.8% and 46.2%, respectively. In a pediatric series from Chile, we have previously reported 8 cases of PTLD out of 157 pediatric LT younger than 15 years-old (5%). Half of them occurred during the first 2 years pot-LT, 5 presented with abdominal involvement and 2 with thoracic masses.

Reduction of immunosuppression was indicated in all cases and 2 patients received Rituximab. One patient presented rejection, 4 responded to treatment and 3 of them died (37.5% mortality rate) due to progression of disease and infection [30].

The clinical presentation of PTLD is related to the disease location and the clinical stage at the time of diagnosis. The diagnosis is difficult and requires a high clinical suspicion, a complete history and physical examination, with laboratory exams, imaging (CT, MRI, PET) and biopsies. A routine histological evaluation of the compromised site should always be complemented with detection of EBV within the tissue, as well as immunophenotyping to determine lymphocyte lineage markers (B or T cell) and the presence of CD20 antigen, all of which will be important at the time of treatment selection [28].

The diagnosis of PTLD impacts significantly patient survival, but with the advent of new therapies, the survival rate has improved (28). The approach requires a multidisciplinary management, that leads initially to a significant reduction in IS to the lowest tolerated dose to avoid graft rejection. In those with localized PTLD, surgery or local radiation therapy should be considered and also other alternatives like antivirals (acyclovir and ganciclovir), passive antibody (intravenous immunoglobulin) and in the most recent years the use of rituximab (a monoclonal antibody against CD20- a B lymphocyte-specific antigen) whether in monotherapy or combined with cytotoxic chemotherapy (like CHOP: cyclophosphamide, hydroxydaunomycin, Oncovin, and prednisone). Complete remission rates vary from 42% to 92% (8, 28). Although better long-term results are achieved with cytotoxic combination chemotherapy, the treatment- related mortality can be quite high (13% to 50%), mostly related to infectious complications.

c) Other solid DNM´s

Other published studies with a long-term follow-up of LT recipients describe in more detail the incidence of other less common DNM´s. An extensive surveillance protocol was evaluated in 779 consecutive adult LT recipients (235 women, mean age 53 years) in a single center in Austria (1982-2007), with a mean follow-up of 4,1 years (range 0-24 years) [30]. Overall, 96 LT recipients (12.3%) developed 105 malignancies [31]. The cumulative risk of DNM´s was 10% at 5 years, 24% at 10 years, 32% at 15 years, and 42% at 20 years after LT. The median time from LT to first DNM´ss was 4,4 year (range 0,21-19,6 years). In 14 patients (14,6%) the DNMs was diagnosed within the first year. The most frequent tumor types were skin (17%), lung (16%), oropharyngeal (11%) and prostate cancer (11%). The median survival of patients with de novo non-skin cancers was 3.1 years after diagnosis. After introducing an intensified surveillance protocol, the detection rate of DNM´s increased from 4.9% to13% and more DNMs were diagnosed in earlier stages, which algo was associated with an

improvement in the median survival time from 1.2 to 3.3 years. This study has emphasized the important role of implementing an intensified surveillance protocol in post LT patients [31].

7. Surveillance Of De Novo Neoplasia

Screening is important at attempting to reduce the burden of malignancy in post LT patients, which improve cancer outcomes [8, 31] (Table 2). Surveillance for LT patients should include annual examination for skin cancer, annual colonoscopy for patients with bowel inflammatory diseases, annual otolaryngology evaluation and chest CT for smokers or patients with smoking history. Women recipients should have annual and Papanicolaou and gynecological evaluation and over 45 years old, annual mammography is recommended. Men over 50 years old should have annual prostate specific antigen. Abdominal ultrasound is recommended to detect de novo Hepatocarcinoma. For children with history of episodes of acute rejection, a frequent physical exam should be performed, and a body CT has to be done if PTLD is suspected [8, 15]

Due to lower life expectancies of LT patients, the application of general population guideline is controversial and, in some cases, not evidence based, indeed, within the general population, patients with life expectancies <5–10 y are less likely to benefit from cancer screening, raising the possibility of harm from ineffective screening programs. The individual clinical context of the patient must always be evaluated, with consideration of personal values, risk tolerance, and the consequences of "overdiagnosis".

Table 2: General screening recommendations for adult post LT patients. (adapted/permits ref. 32)

Cancer	Screening	Frequency	SOR and LOE
Skin Cancer (non melanoma)	Dermatologist exam	Annual	SR / Moderate
Oropharingeal Cáncer	ENT	Annual (in smokers) Every 2 years (in nonsmokers)	SR / Low
Prostate	PSA and Urology exam	Annual in men > 50 years old (but not clear at all)	SR /High
Breast	Mammogram (& Ultrasound) in > 40 years	Annual	SR / High
Cervical/uterine	Pap smear and Gynecologist exam in > 20 years	Every 1-3 years (depends of associated risk factors and HPV)	SR / High
Colorectal	Colonoscopy with biopsies	Annual (in patients with PSC and IBD	SR / High
	Colonoscopy	Frequency varies upon local practices for general population (every 5 years in > 50 years)	SR / Moderate
Lung	Low-dose CT thorax	In smokers or past history (Every 1-2 years).	SR / High
		In non-smokers	No clear Rm
Gastric or esophageal	Unclear	Unclear (depends on personal history, H pylori status, previous atrophy or intestinal metaplasia, and country).	No clear Rm
De novo HCC	Ultrasound	6-12 months (in patients without prior HCC who develop cirrhosis of the allograft).	SR / High
	or		
	CT scan (depends on history)	In those transplanted for HCC, recurrence depends on other factors, like stage and treatments before LT, and explant findings.	SR /High
PTLD	History and physical exam for all LT patients (constitutional symptoms, lymphadenopathy, organomenomegaly q 3 months first 1-2 years).		
	Monitor EBV DNA levels in the first year post LT, in EBV negative children.		SR / Moderate
	In suspicious cases a body CT scan should be performed.		
	In other post LT patients: unclear recommendations		No clear Rm

Abbreviations: HCC, hepatocellular carcinoma; IBD, inflammatory bowel disease; PSC, primary sclerosing cholangitis; SOR, strength of recommendation; LOE, level of evidence; SR, strong; Rm: recommendations, CT: computed tomography; PSA: prostate specific antigen

8. Conclusions

The risk of developing de novo malignancies post-LT is around 1% per year; with approximately 3% to 15% of LT recipients developing new malignancy at some point after LT. De novo malignancy post-LT is the second leading cause of death post-LT, following cardiovascular complications, being skin cancer is the most common malignancy (accounting for 6% to 20% of all cancers after transplant) , followed by PTLD (30 -fold increased risk of hematologic malignancies compared to the general population). Finally, LT recipients face a two-fold increased risk of solid organ malignancies (colon, lung, gastric, breast, etc), hence the importance of regular screening strategies

Risk factors for DNM´s include long-term immunosuppressive therapy, patient demographics, cause of chronic liver disease, smoking and alcohol abuse, and pre-existing premalignant

conditions

The increased incidence of DNM´s in LT recipients demands minimizing immunosuppressant usage, stratify recipients at higher risk and implement a careful and cost-effective long-term screening protocol to help facilitate diagnosis at an earlier stage of disease to offer favorable outcomes for LT recipients.

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