Table 2. Logistic regression analysis of factors influencing prolonged renal failure.

| Parameter | Odds-ratio | CI [95%] | p value |
|--|------------|----------------|---------|
| Lowest creatinine clearance (during the first 6 months) | 0.49 | [0.32 - 0.74] | 0.001 |
| Chronic GVHD* | 5.58 | [1.90 - 16.40] | 0.01 |
| CMV Infection [†] | 3.29 | [1.13 - 9.59] | 0.03 |
| Total duration of cyclosporine therapy (days) | 1.1 | [1.02 - 1.20] | 0.05 |

*GVHD: graft-versus-host disease; [†]CMV: cytomegalovirus.

observed in 58% of PRF patients versus 38% of patients with normal renal function (p=0.04), no specific data focusing on renal function, such as urinalyses, were available. When entered into the logistic regression model, 4 variables with an unfavorable impact remained statistically significant: chronic GVHD, CMV infection, Cs-A exposure and the lowest creatinine clearance during initial hospital stay (Table 2). Analyses of prognostic factors for CRF were inappropriate because of the low number of patients. Nevertheless, TBI seemed to play a negative role, 90% of the CRF patients having received TBI versus only 55% of patients with preserved renal function (p=0.05).

Our study focused on late renal failure and identified chronic GVHD and CMV infection as crucial events influencing the risk of PRF.10 This concept of PRF is described for one of the first times: the late normalization of renal function in a subset of patients could be explained by the same mechanisms as those observed after malignant hypertension⁵ or the progressive withdrawal of nephrotoxic drugs. TBI did not have a significant impact on PRF but the use of irradiation affected the incidence of CRF, confirming the late impact of radiation therapy on the kidneys.67 The long-term nephrotoxicity of Cs-A does not seem to be linked to chronic GVHD; these 2 factors were independent in the multivariate analysis. The high incidence of PRF among patients with chronic GVHD is in favor of specific renal impairment even if confounding factors cannot be excluded.⁵ The CMV status of the donor and the recipient had a clear influence on survival after allogeneic HSCT.⁴ We identified CMV infection as a strong independent risk-factor for the occurrence of PRF. Drugs used for CMV treatment are nephrotoxic in high concentrations and the correlation between CMV infection and PRF may also be due to this treatment.

The interweaving between CMV infection, GVHD and the prolonged use of Cs-A prevent us from drawing definitive conclusions. Examining the effect of early renal injury we found that a decrease of 10 mL/min in creatinine clearance during the first 3 months posttransplant was associated with a 2-fold higher risk of developing PRF, but late recovery of renal function can occur.

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Key words: kidney failure, allogeneic hematopoietic stem cell transplantation, transplant complications, radiation injuries, late effects.

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Stem Cell Transplantation

A psychosocial assessment interview of candidates for hematopoietic stem cell transplantation

There is evidence that psychosocial issues are associated with poorer compliance and higher mortality in the post-transplant period. Thus, psychosocial assessment of candidates for transplantation is an important way of detecting early those patients who are susceptible to developing psychiatric symptoms and psychosocial difficulties during treatment. We developed a psychosocial structured interview to assess candidates for hematopoietic stem cell transplantation. The interview is a short and comprehensible instrument, requiring an average of 50 minutes to be completed.

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Hematopoietic stem cell transplantation (HSCT) is a complex procedure requiring psycho-oncological interventions at a variety of stages, e.g., during crises due to graft-versus-host disease or after discharge from the hospital. There is evidence that psychosocial issues are associated with poorer compliance and higher morbidity in the post-transplant period.¹⁻⁵ In the last decade, there has been a great increase in the literature in this field, but few reports have used structured psychosocial interviews to assess HSCT candidates. Hoffman et al.6 developed a psychodynamically-oriented psychiatric interview that needs 2 to 3 consultations to be carried out. The aim of this study was to develop a psychosocial structured interview to assess HSCT candidates. We designed the Psychosocial Assessment Interview of Candidates for Hematolopoietic Stem Cell Transplantation (PAIC-HSCT). This is a simple, short and comprehensible instrument adapted to a population with unfavorable living conditions and limited understanding abilities, whose education is, in many cases, incomplete.⁷ The content of the PAIC-HSCT is based on items of the scales Psychosocial Assessment of Candidates for Transplantation (PACT) scale.8 on the Transplant Evaluation Rating Scale (TERS)⁹ and on some questions of the Structured Interview for Renal Transplantation (SIRT).¹⁰ We only considered those questions of the SIRT which could be relevant to HSCT. The PACT and TERS are brief and comprehensive scales that can be completed by the interviewer in about 2 minutes. The PACT has 8 items, each rated on a 5-point scale and the TERS has 10 items, rated 1-3. They are standardized instruments that can be used to classify patients' level of psychosocial adjustment to transplantation. However, they have neither a glossary nor an interview schedule to give clinicians the necessary guidance before rating the distinct dimensions covered by these instruments.

We submitted the PAIC-HSCT to the judgment of 13 professionals (3 hematologists, 5 HSCT mental health professionals, 4 consultation-liaison psychiatrists and 1 psychologist), in order to analyze the interview with regard to: i) content; ii) explicitness; iii) lay-out; iv) efficiency to provide data to fill in the PACT and TERS. Their suggestions and comments were analyzed and we made the appropriate changes in the instrument. In a pilot study the PAIC-HSCT was administered by the first author to 30 HSCT candidates (27 allogeneic and 3 autologous).

The final version of the PAIC-HSCT has 147 items comprising the following domains: i) identification, social and demographic data: ii) comprehension of the illness; iii) comprehension of the transplantation; iv) medical compliance; v) life style; vi) coping strategies; vii) mental status examination; viii) psychiatric history; ix) family history; x) social and family support; xi) expectation of the transplantation. It is composed of open and multiple choice questions. The interview required an average of 50 minutes to be completed. Only one patient in the pilot study considered the interview long-winded and all of them considered it helpful in making them reflect upon their illness and the transplant process. The domains Comprehension of the transplantation and Social and family support are presented in Tables 1 and 2, respectively. The PAIC-HSCT guided clinicians through the interview process by providing a comprehensive structure. It facilitates a clinician's ability to conduct an evaluation in a time-efficient manner.

Table 1. Domain Family and Social Support of the PAIC-HSCT.

- In some of the stressful situations you have been through, who has given you emotional support?
- 2. In financial difficulty, who has given you economic support?
- Since the beginning of your disease, who has given you emotional support?
- 4. Since the beginning of your disease, who has given you financial support?
- Who will take care of you (caregiver) during your hematopoietic stem cell transplant (HSCT)?
- Did your caregiver attend consultations with you? Do you think he/she was well informed about the care you will need during your recovery?
- 7. Please, tell me about the relationship between you and the caregiver.

 Table 2. Domain Comprehension of the Transplant of the PAIC-HSCT.

- 1. What is bone marrow?
- 2. What is a hematopoietic stem cell transplant and how can it help your health?
- Considering your clinical condition, what are the advantages and disadvantages of the HSCT?
- 4. Do you know why you have been chosen to undergo a HSCT?
- 5. Can you tell me what you know about what will happen during the transplant once you are in hospital?
- 6. Can you tell me what you know about the period following your discharge from hospital?
- 7. What are the possible side effects of the medicines used during the transplantation?
- 8. Do you think you understand all the risks of the treatment you are going to go through?
- 9. What are the possible complications and late effects of a HSCT?
- Did you have the chance to meet somebody who has already undergone a HSCT?
- 11. How was this meeting?
- 12. Do you believe you have received enough information to make a decision about HSCT?

It may also be useful for training clinicians and research purposes. It can be useful to fill in the PACT and TERS scales and therefore for identifying candidates who may be eligible for HSCT or who will need intensive psychosocial care during treatment. The PAIC-HSCT is intended to improve candidates' selection and help early detection of patients susceptible to developing psychiatric symptoms and psychosocial difficulties during treatment, increasing the chances of satisfactory compliance. A copy of the PAIC-HSCT can be obtained on request to the authors.

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Key words: hematopoietic stem cell transplantation (HSCT), psychosocial assessment, psychosocial interview.

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Epidemiology

No relationship between hepatitis C infection and risk of myeloid malignancy

The etiology of myeloid malignancies is related to chromosomal damage caused by irradiation, alkylating agents, viral infection and so forth;¹ however, few clinical studies have been published on the association between viral infection and the development of myeloid malignancies.

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Hepatitis C virus (HCV) is the major pathogen of posttransfusion and sporadic non-A, non-B chronic hepatitis, and one of the most important causes of chronic liver disease.² It involves many organs, causing extrahepatic manifestations.² Crovatto *et al.* demonstrated that peripheral blood neutrophils are the replication sites of HCV,³ while it remains unknown whether the infection occurs at the level of the stem cells or subsequently during myeloid cell differentiation. A few clinical studies suggest a weak, non-significant association between acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), and antibody to HCV;⁴⁵ however, it remains unknown whether HCV infection might contribute to the development of myeloid malignancies. We conducted a hospital-

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based case-control study to evaluate this association.

We selected 94 patients with myeloid malignancies from 326 consecutively registered patients with hematologic malignancies at Toranomon Hospital between 1995 and 2001. Myeloid malignancies were classified according to the International Classification of Diseases 10th version (ICD-10). Myeloid leukemia (C92), monocytic leukemia (C-93), acute erythroleukemia (C94.0), megakaryocytic leukemia (C94.2) and myelodysplastic syndrome (D46) were included in this study. All the patients had newly diagnosed myeloid malignancies, and had never received any chemotherapy. Controls were selected randomly from hospitalized orthopedics patients (n=188) and otolaryngology patients (n=188), each group matched for age, sex and year of visit with a 1:2 case-control ratio. We excluded patients with a history of malignancy. Age was further adjusted as a continuous variable in conditional logistic regression analysis. The following data were extracted from medical records; age, sex, smoking habit, alcohol use, hepatitis B virus surface (HBs) antigen, anti-HCV antibody (anti-HCV-Ab), anti-human T-cell leukemia virus (HTLV)-1 antibody, anti-HIV antibody, and a history of malignancy. The definition of HCV infection was positive anti-HCV-Ab by enzyme immunoassay (EIA-I or EIA-II, Ortho Diagnostic Systems, Tokyo, Japan) on admission. To minimize unknown biases, we used two independent control groups in which each case was matched to four individuals for age, sex, and year of admission.

All statistical analyses were performed with STATA, version 7. (STATA Corp., College Station, TX, USA). Bivariate analyses were performed with χ^2 , Fisher's exact, or Wilcoxon's signed-rank test. Attribution of HCV infection was evaluated in terms of odds ratios (OR) and 95% confidence intervals (CI). A conditional logistic regression model was applied to estimate ORs and 95% CIs. The study protocol was approved by the institutional review board.

The patients' characteristics are shown in Table 1. Five patients with myeloid malignancies had HCV infection. The prevalence of HCV infection in cases (5.3%) was comparable with that in orthopedic (6.4%), otolaryngology (6.9%) and combined controls (6.6%) (Table 1). Age-adjusted odds ratios for seropositivity of HCV are shown in Table 2. There was no significant association between seropositivity of HCV and development of myeloid malignancies.

Our study does not support an association between HCV infection and development of myeloid malignancies. These findings are comparable with those of previous reports.⁴⁵ While further evaluation of the association is necessary, currently available observations, including ours, suggest that HCV infection is unlikely to increase the rate of myeloid malignancies. This contrasts with the association between HCV infection and lymphoid malignancies.¹ Although the development of both myeloid and lymphoid malignancies is considered to be affected by genotoxic factors such as viral infections, irradiation, and chemotherapeutic agents, our observation suggests that the mechanisms of tumorigenesis are different between lymphoid and myeloid malignancies.

A case-control study is suitable for studying a rare disease such as myeloid malignancies; however, this study has several problems to be discussed. First, it was hospital-based, and possibly affected by an unrecognized bias in the case and the control groups. Secondly, data on