

Early infection in post-autologous hematopoietic stem cell transplant patients

Princess Noorah Oncology Center experience

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ABSTRACT

الأهداف: يعتبر زرع الخلايا الجذعية المكونة للدم هو معيار الرعاية في العديد من الأورام الخبيثة مثل الأورام الملمفاوية والورم النقوي الحاد. في المملكة العربية السعودية ، تم تصنيف كل من سلطان الغدد الليمفاوية هودجكين وغير هودجكين على أنها الحمضة الأكبر شيوعاً بين الذكور والإثاث. قد تؤثر عدة عوامل على التعافي المبكر لجهاز المناعة لدى مرضى زراعة الخلايا الجذعية الذاتية. تقييم هذه الدراسة عوامل الخطير للعدوى البكتيرية والفطرية والفيروسية بين المرضى الذين زرعوا نخاع العظم ذاتياً.

المهنية: هذه الدراسة عبارة عن تصميم ارتقائي استعادي لمجموعة تضم ١٥٠ مريضاً بالغاً يخضعوا لعمليات زرع ذاتية في مركز الأميرة نورة للأورام بين عامي ٢٠١٤ و٢٠٢٠.

النتائج: تشير نتائج الدراسة إلى أن انتشار العدوى البكتيرية اختفى بشكل كبير غير حالة المرض المختلفة قبل العلاج الكيماوى حيث كان المرضى الذين يعانون من الإنفلونزا أكثر عرضة للإصابة بعدوى بكتيرية. اختفى متوسط أيام استعادة النشاط النسخاء بشكل كبير بين أولئك الذين أصيبوا بعدوى بكتيرية وأولئك الذين لم يصابوا بها. ومن المثير للاهتمام أن عدوى الالتهاب الرئوي السابقة كان لها علاقة إيجابية بعدد أيام المköث في المستشفى.

الخلاصة: العدوى البكتيرية هي النوع السائد من العدوى بين المرضى يعكس البحث الممارسة الأصلية ويبليغ عن الحالات الفردية لمرضي الزراعة الذاتية من حيث انتشار وأنواع العدوى التي يعاني منها هؤلاء المرضى.

Objectives: To assess local epidemiology and risk factors for bacterial, fungal, and viral infections among the autologous bone marrow transplant population.

Methods: This study is a retrospective correlational cohort design comprising 150 adult patients who underwent autologous transplants at Princess Noorah Oncology Center, Jeddah, Saudi Arabia between 2014 and 2020.

Results: The study findings indicate that bacterial infection prevalence differed significantly across the different disease status pre-salvage as patients with the relapsed disease were more likely to have bacterial

infections. The median of engraftment days differed significantly between those who had a bacterial infection and those who did not. Interestingly, previous pneumonia infection had a positive relationship with the number of hospital stays.

Conclusion: Bacterial infections are the dominant type of infection among the autologous patient population. The research reflects authentic practice and reports unique characteristics of autologous transplant patients in terms of the prevalence and types of infection these patients experience.

Keywords: bone marrow transplantation, lymphoma, infection, relapsed, myeloma

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Autologous hematopoietic stem cell transplantation (ASCT) is considered the standard of care in relapsed/refractory lymphoid malignancies, multiple myeloma disease, and some solid tumors in children, such as neuroblastoma. Autologous hematopoietic stem cell transplantation represents 58% of all bone marrow transplants (BMT) in Europe (plasma cell disorders,



46%; non-Hodgkin's lymphoma [NHL], 30%; Hodgkin's disease, 11%). Autologous hematopoietic stem cell transplantation is also considered the gold standard for eligible patients diagnosed with myeloma. In spite of the introduction of several new regimens for myeloma, the transplant remains a major component of the therapeutic plan to prolong progression-free survival.¹ In Saudi Arabia, both Hodgkin lymphoma (HL) and NHL were rated among the top 5 most frequent cancer types among males and females.² Lymphomas and multiple myeloma accounted for 11.8% of deaths among the Saudi population in 2014.³ Complications are expected during and shortly after the transplant course. One major complication is the occurrence of infection, which is directly related to high doses of chemotherapy and the consequent major immunosuppression, breach of the mucous membrane barrier in the gastrointestinal tract, and line-related infections. Therefore, infection occurs in almost all patients due to a weakened immune system and prolonged neutropenia, and has been proven to be a major cause of mortality during therapy. Some factors that have been demonstrated to increase the risk of infection in transplant patients include conditioning regimen, disease status pre-transplant, patient comorbidities, and associated immunodeficiencies.⁴ Data concerning the factors affecting early immune recovery in ASCT are limited. Although numerous factors are associated with early recovery, those factors are poorly recognized. Therefore, identification may enhance early immune recovery and will be helpful in improving the long-term outcome in these patients.⁵ The most common infection in post-transplant is bacterial, which can involve gram-positive or gram-negative bacteria, fungal or viral in nature. The transplant course centers around conditioning chemotherapy or high dose therapy. One major side effect of conditioning chemotherapy is bone marrow damage (neutropenia); therefore, collected stem cells are reinfused to help the patient recover and shorten the period of neutropenia and infection. Neutropenia in the pre-engraftment period, accompanied by the disruption of mucocutaneous barriers, is an important predisposing factor for infections that can lead to morbidity.⁶ Other contributing factors included age, disease status, lines of chemotherapy, number of CD34, engraftment, and duration of neutropenia.

The aim of this study was to assess local epidemiology and risk factors for bacterial, fungal, and viral infections among the autologous BMT population. Due to the vulnerable immune system of those patients, establishing infectious data auditing on a local level is essential. Furthermore, the patients' related factors certainly do carry some local variation based on the relatively unique patients' local characteristics. Developing a reliable predictive measure for the occurrence of infections would be highly useful, along with identifying low-risk patients who could potentially be provided ASCT on an outpatient basis.

Methods. This study was a retrospective correlational cohort design. All cases were collected from Princess Noorah Oncology Center (PNOC), Jeddah, Saudi Arabia. The sample included all autologous BMT patients from March 2014 until June 2020. Purposive sampling, a type of nonprobability sampling, was used to collect 150 patients.

The inclusion criteria was autologous BMT patients who had transplant at PNOC. To ensure a representative sample and to achieve the study's goal, all transplanted patients were included in the study. The researcher collected the following data: gender; diagnosis (HL, NHL, and multiple myeloma); disease status; relapsed or refractory (no response to treatment or treatment resistance); number of lines salvage chemotherapy age; diabetes; previous fungal infection; CD34; engraftment; cytomegalovirus (CMV) status pre-BMT; neutropenic fever; pneumonia (neutropenic colitis – ileitis), bacterial infections (gram positive [GP] infections, gram negative [GN] infections *Clostridium difficile* [*C. diff*]); fungal infections *Candida aspergillosis*; fungal infections radiologic - cultures proven: viral infections, herpes simplex viruses (HSV), human alphaherpesvirus-varicella zoster virus, human immunodeficiency virus, respiratory syncytial virus influenza; and parasitic infections and parasites. All data were collected from patient records from day 0 (referred to as transplant day) until 30 days post-transplant. This time frame was selected because it represented the expected time for an infection to occur.⁷

Statistical analysis. The data were analyzed using IBM SPSS Statistics for Windows, version 25 (IBM Corp, Armonk, N.Y., USA), which included descriptive statistics as mean, median, and mode. A *p*-value <0.05 was considered statistically significant. To assess differences between categorical variables in the same population, the Chi-square and Fisher's exact tests were used. The Mann-Whitney U test was also used to compare the means of engraftment, CD34 count,

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and length of stay in the hospital between infected and uninfected patients. All of the tests mentioned have been used based on the type of variable and whether or not it meets parametric assumptions. Participants' privacy and confidentiality were maintained through the anonymity of names and file numbers. International Review Board approval was obtained from the Institutional Review Board at the Ministry of National Guard Health Affairs.

Results. The data analysis included 150 patients, 50.7% were ages between 21 and 40, 63.3% males, and 86% did not have diabetes. In terms of diagnosis, 44% had HL with NHL, and multiple myeloma accounting for the remaining 51.4%. Furthermore, 56 (37.7%) patients had refractory disease, while 44 (29.3%) patients relapsed. Before undergoing transplant, 47.3% of the patients received one line of salvage chemotherapy. In comparison, 14.7% of the sample received 2 lines of salvage chemotherapy (Table 1). Table 2 shows the prevalence of bacterial infections with 95 % confidence intervals (CI).

In Table 1, 3 and 4, the findings indicate that bacterial infection (gram-positive and gram-negative) was the dominant type among the group (40%). No viral infection was found among the sample. Only one parasitic infection was documented and was consequently excluded from the analysis. Furthermore, there was a significant correlation between the prevalence of bacterial infection and disease status prior to salvage ($p=0.034$). There is a positive relationship between patients with relapsing disease and bacterial infections, ($p=0.06$). Nonetheless, patients in the multiple myeloma group were less likely to have bacterial infections. Additionally, there was a strong association between patients with a history of line-related infection and bacterial infections ($p<0.001$). The median of engraftment days differed significantly among those who did or did not have a bacterial infection ($U=2101.5$, $Z=2.5$, $p=0.013$). Similarly, the median of time to discharge showed significant differences among those who did or did not have a bacterial infection ($U=1943.5$, $Z=3.2$, $p=0.001$). Additionally, median time to discharge varied among those who did or did not have pneumonia ($p=0.033$).

Discussion. The study results revealed that overall infections were bacterial gram-positive and negative. Similar to other study findings which reported a higher finding of bacterial infections, representing 70% of the patients in that study.⁸ The non-existence of viral infection reflects improved pre-transplant serological clearance which include the followings tests (hepatitis,

Table 1 - Baseline characteristics of participants and their disease status.

Variables	n	(%)
<i>Age</i>		
Up to 20 years	15	(10.0)
21-40 years	76	(50.7)
Above 40 years	59	(39.3)
Mean	37.5	
SD	±13.5	
Range	54	
<i>Gender</i>		
Male	95	(63.3)
Female	55	(36.7)
<i>Diabetes mellitus</i>		
Yes	21	(14.0)
No	129	(86.0)
<i>Diagnosis</i>		
HL	66	(44.0)
NHL	37	(24.7)
MM	40	(26.7)
Pomes syndrome	3	(2.0)
APL	3	(2.0)
Germ cell tumor	1	(0.7)
<i>Disease status pre-salvage for HL and NHL</i>		
Relapsed	44	(29.3)
Refractory	56	(37.3)
NA	50	(33.3)
<i>Number of lines (salvage chemotherapy)</i>		
One line	71	(47.3)
Two lines	22	(14.7)
Three lines	9	(6.0)
Four lines	1	(0.7)
NA	47	(31.3)

SD: standard deviation, HL: Hodgkin lymphoma, NHL: non-Hodgkin lymphoma, MM: multiple myeloma, APL: acute promyelocytic leukemia, NA: not applicable (multiple myeloma group)

Table 2 - Prevalence of bacterial infections with 95% confidence interval (CI).

Infection	Prevalence (95% CI)
Neutropenic fever	98.7 (96.7-100)
Neutropenic colitis/ileitis	7.3 (3.3-12)
Pneumonia	3.3 (0.7-6.7)
Gram positive infection	12.7 (7.4-18)
Gram negative infection	30 (22.7-37.3)
<i>Clostridium difficile</i>	9.3 (5.3-14.7)

human immunodeficiency virus, syphilis, toxoplasmosis, varicella zoster, CMV, EBV, HSV, HTLV1/11, and brucella), plus the utilization of prophylactic antiviral therapy. This result indicates that viral infection is less common among the autologous population. However,

Table 3 - Univariate analysis for baseline and disease characteristics and infectious complications in patients who underwent autologous hematopoietic stem cell transplant modified.

Characteristic	Neutropenic fever		P-value	Neutropenic colitis/ileitis		P-value
	Yes n (%)	No n (%)		Yes n (%)	No n (%)	
Gender						
Male	93 (97.9)	2 (2.1)	0.532*	5 (5.3)	90 (94.7)	0.212*
Female	55 (100.0)	0 (0)		6 (10.9)	49 (89.1)	
Age category						
Up to 20 years	15 (100.0)	0 (0)		1 (6.7)	14 (93.3)	
21-40 years	76 (100.0)	0 (0)	0.344*	5 (6.6)	71 (93.4)	0.900*
41 years and above	57 (96.6)	2 (3.4)		5 (8.5)	54 (91.5)	
Diabetes mellitus						
Yes	21 (100.0)	0 (0)	0.999*	0 (0)	21 (100.0)	0.364*
No	127 (98.4)	2 (1.6)		11 (8.5)	118 (91.5)	
Patient diagnosis						
HL	66 (100.0)	0 (0)		5 (7.6)	61 (92.4)	
NHL	37 (100.0)	0 (0)		4 (10.8)	33 (89.2)	
MM	38 (95.0)	2 (5.0)	0.221*	2 (5)	38 (95.0)	0.548*
Pomes syndrome	3 (100.0)	0 (0)		0 (0)	3 (100)	
APL	3 (100.0)	0 (0)		0 (0)	3 (100)	
Germ cell tumor	1 (100.0)	0 (0)		0 (0)	1 (100)	
Disease status pre-salvage for HL and NHL						
Relapsed	44 (100)	0 (0)		1 (2.3)	43 (97.7)	
Refractory	56 (100.0)	0 (0)	0.194*	8 (14.3)	48 (85.7)	0.066*
NA	48 (96.0)	2 (4.0)		2 (4.0)	48 (96.0)	
Number of lines (salvage chemotherapy)						
One line	71 (100.0)	0 (0)		5 (7)	66 (93.0)	
Two lines	22 (100.0)	0 (0)		3 (13.6)	19 (86.4)	
Three lines	9 (100.0)	0 (0)	0.339*	1 (11.1)	8 (88.9)	0.458*
Four lines	1 (100.0)	0 (0)		0 (0)	1 (100)	
NA	45 (95.7)	2 (4.3)		2 (4.3)	45 (95.7)	
ICU admission						
Yes	3 (100.0)	0 (0)	0.999*	0 (0)	3 (100.0)	0.999*
No	145 (98.6)	2 (1.4)		11 (7.5)	136 (92.5)	
Line-related infection						
Yes	12 (100)	0 (0)	0.999*	0 (0)	12 (100.0)	0.601*
NO	136 (98.6)	2 (1.4)		11 (8.0)	127 (92)	
CD34						
Median (range)	4.54 (30.61)	8.94 (6.76)	0.159	3.92 (8.5)	90 (94.7)	0.091
Engraftment						
Median (range)	10 (19.0)	10.50 (1.0)	0.650	9 (2.0)	49 (89.1)	0.157
Discharge						
Median (range)	14 (46.0)	12.50 (1.0)	0.206	13 (16.0)	14 (93.3)	0.988

HL: Hodgkin lymphoma, NHL: non-Hodgkin lymphoma, MM: multiple myeloma, ICU: intensive care unit, APL: acute promyelocytic leukemia, NA: not applicable (multiple myeloma group), *Chi-square and Fisher's exact tests

disease-related factors such as the presence of relapsed disease correlated with a higher risk of infection, which probably reflects the number of salvage chemotherapy lines the patients might have received that deepened their immunosuppression. The finding is related to the reports by Valtola et al⁹ and Lakatos et al,⁵ who noted that relapsed disease was a factor affecting early recovery. On the other hand, in our study, the multiple

myeloma group had a lower risk of infection, which is contrary to the results reported by Park et al,¹⁰ showing that the rate of infection was higher among patients with multiple myeloma. We hypothesized that this outcome could be a reflection of better patient selection plus the utilization of more novel induction therapies in myeloma patients prior to transplant. We found that line infection is associated with bacteria. Ali et al¹¹

Table 4 - Univariate analysis for baseline and disease characteristics and infectious complications in patients who underwent autologous hematopoietic stem cell transplant modified.

Characteristics	Pneumonia		P-value	Bacterial		P-value
	Yes n (%)	No n (%)		Yes n (%)	No n (%)	
Gender						
Male	3 (3.2)	92 (96.8)	0.999*	42 (44.2)	53 (55.8)	0.732
Female	2 (3.6)	53 (96.4)		22 (40.0)	33 (60.0)	
Age category (years)						
Up to 20	1 (6.7)	14 (93.3)		6 (40.0)	9 (60.0)	
21-40	4 (5.3)	72 (94.7)	0.162*	32 (42.1)	44 (57.9)	0.971
≥41	0 (0)	59 (100)		26 (44.1)	33 (55.9)	
Diabetes mellitus						
Yes	0 (0)	21 (100)		11 (52.4)	10 (47.6)	
No	5 (3.9)	124 (96.1)	0.999*	53 (41.1)	76 (58.9)	0.351
Patient diagnosis						
HL	2 (3)	64 (97.0)		27 (40.9)	39 (59.1)	
NHL	3 (8.1)	34 (91.9)		21 (56.8)	16 (43.2)	
MM	0 (0)	40 (100.0)	0.309*	13 (32.5)	27 (67.5)	0.223*
Pomes syndrome	0 (0)	3 (100.0)		1 (33.3)	2 (66.7)	
APL	0 (0)	3 (100.0)		1 (33.3)	2 (66.7)	
Germ cell tumor	0 (0)	1 (100.0)		1 (100.0)	0 (0)	
Disease status pre-salvage for HL and NHL						
Relapsed	1 (2.3)	43 (97.7)		25 (56.8)	19 (43.2)	
Refractory	3 (5.4)	53 (94.6)	0.627*	24 (42.9)	32 (57.1)	0.034
NA	1 (2.0)	49 (98.0)		15 (30.0)	35 (70)	
Number of lines (salvage chemotherapy)						
One line	3 (4.2)	68 (95.8)		33 (46.5)	38 (53.5)	
Two lines	1 (4.5)	21 (95.5)		10 (45.5)	12 (54.5)	
Three lines	0 (0)	9 (100.0)	0.896*	5 (55.6)	4 (44.4)	0.291
Four lines	0 (0)	1 (100.0)		1 (100.0)	0 (0)	
NA	1 (2.1)	46 (97.9)		15 (31.9)	32 (68.1)	
ICU admission						
Yes	0 (0)	3 (100.0)	0.999*	2 (66.7)	1 (33.3)	
No	5 (3.4)	142 (96.6)		62 (42.2)	85 (57.8)	0.576*
Line-related infection						
Yes	0 (0)	12 (100)	0.999*	12 (100)	0 (0)	<0.001
NO	5 (3.6)	133 (96.4)		52 (37.7)	86 (62.3)	
CD 34						
Median (range)	3.83 (3.76)	14 (46.0)	0.429	4.72 (12.1)	4.47 (30.61)	0.917
Engraftment						
Median (range)	10 (4.0)	4.61 (30.6)	0.515	10 (15.0)	10.50 (11.0)	0.001
Discharge						
Median (range)	16 (6.0)	10 (19.0)	0.033	15 (46.0)	13 (13.0)	0.013

HL: Hodgkin lymphoma, NHL: non-Hodgkin lymphoma, MM: multiple myeloma, ICU: intensive care unit, APL: acute promyelocytic leukemia, NA: not applicable (multiple myeloma group), *Chi-square and Fisher's exact tests

concluded that bacterial infection was present in 18 out of 108 patients. The number of patients with *C. diff* was minor, 14 patients (almost 9%) . This finding concurs with what is already known on *C. diff* and uncommon among the autologous group and is supported by Rahman et al¹² reported 8 cases who became infected post-transplant.

Almost all patients experienced neutropenic fever pre-engraftment, which is consistent with the findings of 2 studies.^{13,14} In both studies, the vast majority of patients had neutropenic fever. The results highlighted that infection had affected engraftment. However, according to Hassan,¹⁵ multiple factors may affect engraftment. For example, neutrophil engraftment was

affected by weight, stage of disease at diagnosis, number of previous chemotherapy cycles, and pre-transplant radiotherapy. In contrast, platelet engraftment was shown to be affected by the same factors in addition to CD34 dosage and stage of the disease. Our study found no relationship between CD34 infused and engraftment. This result differs from Nath,¹⁶ who asserted that higher dose of CD34+ stem cells was linked to faster neutrophil recovery and engraftment. This outcome could be explained by the earlier use of hematopoietic growth factors and improved supportive and prophylactic antibiotics, which can overcome such a difference. Park et al¹⁰ revealed that hospital stays were longer in patients who experienced bacterial infection, which is identical to our findings. In contrast, Moghnieh et al⁸ found that a patient's average stay was not affected by infection.

Study limitations. The study was retrospective and involved a limited number of patients. However, the research reflects authentic practice and has reported unique characteristics of autologous transplant patients in terms of the prevalence of bacterial infection and prevalence of viral and fungal infections.

We began the auto-SCT program at PNOC in 2014 as an in-patient setting. Many centers around the world have shifted such procedures to an out-patient setting. The occurrence of infections, particularly bacterial infections, is a major impediment to such shifting. The findings of this study could be used to screen patients for out-patient auto-SCT in Saudi Arabia.

In conclusion, the study findings showed that bacterial infections are the most common in autologous patients, especially gram-negative infection. Thus, increasing the awareness of local epidemiology data is essential. A multicenter study on a national level is highly recommended. In addition, the inclusion of allogeneic transplant patients could yield helpful information for the medical professionals who are treating these patients.

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