# • Basic Research

# Relationship between Adherence to Therapeutic Regimen and Clinical Outcomes among Patients Post Hematopoietic Stem Cell Transplantation

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#### Abstract

Background: Hematopoietic stem cell transplantation (HSCT) is a life- saving method for multiple conditions such as cancer, immune disorders, and hematologic diseases. Therapeutic regimen adherence in HSCT patients may be compromised by the complexity of their condition and could influence these patients' clinical outcomes, furthermore, non-adherence rises the risk of mounting serious health outcomes like graftversus-host disease, infection which all lead to readmissions. Aim of the study: The aim of this study is to identify the relationship between adherence to therapeutic regimen and clinical outcomes among patients post hematopoietic stem cell transplantation. Design and Setting: The study design was descriptive correlational research design. The study was carried out in the outpatient clinic of the Bone Marrow Transplantation Unit, Al-Moassat University Hospital, Alexandria, Egypt. Subjects: It was comprised of 80 post HSCT patients. Tools: three tools were used for data collection; Tool I: Sociodemographic and clinical data of Post-HSCT patients, structured interview questionnaire, Tool II: Post hematopoietic stem cell transplantation patients' adherence questionnaire. Tool III: Clinical outcomes assessment sheet. Results: three-fifths of the studied patients (60%) had moderate level of adherence, more than two-thirds of them (70%) had poor clinical outcomes, and there was a statistically significant correlation between patient's level of adherence and their clinical outcomes (p=0.004). Conclusion: the highest percent of the studied patients were highly adhered to follow up visits and prescribed medication regimen, while they were poorly adhered to recommended diet, infection prevention precautions, and social activity precautions. Most of the studied patients had poor outcomes. Recommendation: Routine adherence and clinical outcomes monitoring should be integrated into standard clinical care of post-HSCT.

Key words: hematopoietic stem cell transplantation, adherence, therapeutic regimen, clinical outcome

#### Introduction

Hematopoietic stem cell transplantation (HSCT) is a rapidly evolving method for various disorders such as cancer, immune disorders, and hematologic disorders. This procedure is often the only curative therapy for patients with high risk and/ or relapsed hematological cancers, the two main categories of HSCT are: the autologous which uses the patient's own stem cells, and the allogeneic which uses the stem cells from donors; the allogeneic HSCT is generally more complicated as it is associated with more short and long-term risks than autologous HSCT. It was reported that more than half of 80,000 HSCT worldwide are autologous HSCT, in fact patients undergoing HSCT, particularly allogeneic, may have serious complications. These include acute and chronic graft versus host disease (GvHD), infections, fatigue, weakness, nausea, and poor oral intake. Besides, they often have psychological and social distress such as depression, anxiety, inability to work in addition to financial burden (Jaing, 2011; Niederwieser et al., 2019; Ovayolu et al., 2013).

The treatment for HSCT involves a multifaceted regimen; long inpatient stays, frequent outpatient clinic visits, and extensive supportive therapies such as frequent blood product transfusions, nutritiontherapy, symptom management, and strict infection control. Additionally, patients are prescribed a complex medication schedule like prophylactic medications, immunosuppressant, and supportive medications (National Cancer Institute [NCI], 2016). The medication regimen is complex as the number and types of medications are varied in scheduling of administration for each medication and the frequently changing prescriptions of each (McGrady et al., 2016). Special consideration is given to immunosuppressant medication adherence is one of the leading causes of post-transplant antibody production, acute rejection, and allograft loss (McGrady et al., 2016; Sabaté, 2003).

World Health Organization identifies adherence as "the extent to which a person's behavior-taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider". On the other hand, non-adherence is the extent to which a person's behavior does not follow healthcare provider advices. Adherence aims at promoting healthy lifestyles to optimize health outcomes for patients undergoing HSCT, thus raising awareness about the importance of patients' adherence with a therapeutic regimen will have a positive effect on patient recovery and satisfaction (Hinkle J. & Cheever K., 2014).

After discharge, patients and families should manage and adhere to a complex regimen that is essential to avoid infection and minimize the risk of other complications, non- adherence to prophylactic antimicrobials and isolation precautions while immunocompromised increases the risk of catching a life-threatening infection. In this regard, regression, cognitive impairment, stress, and social isolation are key issues that patients undergoing HSCT may experience and they can lead to negative effects on adherence and managing this complex regimen(**Butow et al., 2010**).

The management of patients post HSCT is a significant challenge; as their needs are changing over time, a continuous reassessment and close monitoring of their condition are essential for early detection of their predisposition to complications that may require

hospitalization, thus it is a major element for all health care provider. Concerning this, the European Society for Blood and Marrow Transplantation has published the first European recommendation which discuss the positive influence that pharmacists can exert on therapeutic adherence (Langebrake et al., 2020). After HSCT procedure, lack of adherence or incorrect administration of medication may trigger serious complications and adverse events, additionally, patients undergoing allogeneic HSCT is compromised by the complexity of the treatment regimen that impacts clinical outcomes (García-Basas et al., 2020; McKenna et al., 2015). So, nursing care of patients post HSCT requires unique knowledge and assessment skills that go beyond basic nursing care of medication administration, teaching, coordination of care, and evaluation of therapy to help them in adherence to therapeutic regimen.

#### Aim of the study:

The study aims to identify the relationship between adherence to therapeutic regimen and clinical outcomes among patients post hematopoietic stem cell transplantation.

## **Research questions of the study:**

Q1. What are the levels of adherence to therapeutic regimen among patients post hematopoietic stem cell transplantation?

Q2. What are the levels of clinical outcomes among patients post hematopoietic stem cell transplantation?

Q3. What is the relationship between adherence to therapeutic regimen and clinical outcomes among patients post hematopoietic stem cell transplantation?

# **II. MATERIALS AND METHOD**

#### **Materials**

## **Research design:**

A descriptive correlational research design was used to conduct this study.

## Setting:

The present study was conducted at the outpatient clinic of the Bone Marrow Transplantation, Al-Moassat University Hospital, Alexandria.

## Subjects:

The required sample size was calculated using G-power (3.1.9.7) program. 72 participants were required for a type 1 error of 0.05 and a power of 80% based on a medium effect size. After accounting for a 10% drop-out rate, the sample size was increased to 80 patients.

# Tools of the study:

Tool I: Socio-demographic and clinical data of Post-HSCT patients, structured interview questionnaire: This tool was developed by the researcher based on reviewing related literature (Gheith et al., 2008; Hoffman et al., 2013; Maziarz & Slater, 2015) to obtain the sociodemographic characteristics and baseline clinical data, it included two parts:

Part 1: Patient's sociodemographic characteristics data sheet: This part included patient's age, gender, level of education, marital status, occupation and income.

Part 2: Patients' Clinical Data sheet: This part included patient's diagnosis, source of transplant, time of transplantation, past medical health history, associated diseases and medications.

**Tool II: Post hematopoietic stem cell transplantation patients**<sup>•</sup> adherence questionnaire: This tool was developed by the researchers after reviewing the related literature (Abdel-Aziz et al., 2019; Gheith et al., 2008; Morrison et al., 2017). This questionnaire includes closed ended questions to assess the patients' level of adherence with the recommended therapeutic program post HSCT. It includes 6 parts as the following:

**Part 1: Adherence to prescribed medication regimen**: Includes questions about the adherence to prescribed medication regimen, it was adopted from the Adherence to Refills and Medication Scale developed by **Alammari et al. (2021)**.

**Part 2: Adherence to the recommended diet:** This part includes 4 items about following diet instructions.

**Part 3: Adherence to prescribed physical activity and exercise**: This part includes 5 items about following the prescribed regimen.

**Part 4: Adherence to precautions for prevention of infections**: This part includes 4 items about precautions for prevention of infection.

Part 5: Adherence to recommended social activity precautions: This part includes 5 items.

**Part 6**: Adherence to recommended medical follow-up visits: This part includes one item. Additionally, there are (6) open ended questions about the reasons for non- adherence with the therapeutic regimen.

## The scoring system:70\54

Each statement was scored using a 4-point Likert- scale (1 = "Never", 2 = "Sometimes", 3 = "Most of the time" and <math>4 = "Always"). A total score of every patient was summed up and converted into a percentage score. The percentage of the total score was classified as follows:

- <50% (Low level of adherence)
- 50% <75% (Moderate level of adherence)
- 75%–100% (High level of adherence)

## Tool III: Clinical outcomes assessment sheet:

It was developed by the researchers after reviewing the relevant literature (García-Basas et al., 2020; Langebrake et al., 2020), it included items related to the HSCT patient's health condition as follows:

- **Part 1:** Current health status (occurrence of post HSCT complications, infection and the incidence of hospital readmissions).
- Part 2: Associated complaints post HSCT.
- **Part 3:** Laboratory investigations (the patient's last 3 values) such as, r e d blood cells, white blood cells, hemoglobin, platelets, SGOT, SGPT, serum urea, serum creatinine, albumin, and C- reactive protein.
- Part 4: Vital signs.

# The scoring system:

The patients were classified according to their clinical outcomes as: "Poor clinical outcome", and "Good clinical outcome". The total average score of every patient was summed up and converted into a percentage score. The percentage of the total score was classified as follows:

- <70% (Poor clinical outcome).
- 70% 100% (Good clinical outcome).

## Method:

- Approval from the Research Ethics committee, Faculty of Nursing, Alexandria University was obtained.
- A written approval to carry out the study was submitted from the Faculty of Nursing to the administrative authorities to collect data and permission was obtained after explaining the purpose of the study.
- Study tools (I, II, III) were developed by the researchers after revieing recent relevant literature.
- Study tools (I, II, III) were submitted to five experts in the field of Medical Surgical Nursing, to test the content validity and the necessary modifications were done.
- Reliability of the study tools was tested usingCronbach's alpha (tool II was 0.887, tool III was 0.898).
- A pilot study was conducted on eight patients at the beginning of the study to test the feasibility and applicability of the tools, these patients were excluded from the actual study sample.
- Each patient was interviewed individually, using tool I to collect the sociodemographic and clinical data of the patients, tool II to assess the patient level of adherence and reasons for non-adherence, and tool III to assess patients' clinical outcomes.
- The duration of the interview ranged from 30-45 minutes.
- Laboratory investigations were recorded from the patients' medical records.
- The data collection started in December 2022 ended at May 2023.

# **Ethical Considerations:**

- Written informed consent was obtained from each patient included in this study after explanation the purpose of the study.
- The patient was informed that his/her participation in the study is voluntary, he/she can withdraw from the study at any time, and his/herwithdrawal would not affect the received care from hospital.
- Anonymity of patients was maintained.
- Privacy of patients was maintained.
- Confidentiality of the collected data was assured.

# Statistical analysis of the data:

Data was fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution, Quantitative data were described using mean and standard deviation. The significance of the obtained results was judged at the 5% level.

The following statistical analysis measures were used:

- 1- Chi-square test: For categorical variables, to compare between different categories.
- 2- Monte Carlo test: for chi-square when more than 20% of the cells have expected sum less than 5.
- **3- Pearson coefficient:** To associate between two normally distributed quantitative variables.

#### **Results:**

**Table (1)** shows percentage distribution of the studied patients according to sociodemographic characteristics, the highest percentage of the studied patients were in the age group from 30 to less than 40 years, males, had secondary education, married, had manual work, from urban areas and their incomes weren't enough with percents of (45%, 60%, 47.5%, 80%, 41.3%, 60%, 68.8% respectively).

**Table (2)** displays percentage allocation of the studied patients according to their clinical data, most of the studied subjects 88.8% diagnosed as having leukemia. Regarding source of transplant, slightly more than three-fifths of the studied patients 62.5% had allogeneic transplantation. 45% of the studied patients had transplantation since more than 24 months, followed by 37.5% of them had transplantation since 6 to less than 12 months. In relation to associated chronic diseases, less than one fifth 18.8% were cardiac patients. Finally, regarding current medications, all the studied patients 100% received post transplantation medications.

**Table (3)** illustrates percentage distribution of the studied patients according to their scores for level of adherence post hematopoietic stem cell transplantation. Regarding adherence to prescribed medication regimen, nearly two thirds of the studied subjects 66.3% had high level of adherence with an average score of  $(3.56 \pm 0.47)$ . Regarding adherence to the recommended diet, more than half of the studied patients 51.3% had low level of adherence with average score  $(2.58 \pm 0.70)$ . In relation to adherence to prescribed physical activity and exercise, slightly less than two-thirds of the studied patients 63.8% had moderate level of adherence with average score  $(2.68 \pm 0.56)$ . As for adherence to the precautions for prevention of infection, more than one-third of the studied patients had low and high level of adherence (40%, 36.3% respectively) with an average score of  $(2.70 \pm 0.63)$ . Obviously, the majority of the studied patients 93.8% had low level of adherence to the recommended social activity precautions, with an average score of  $(1.92\pm0.38)$ , while all of them 100% were highly adhered to the recommended follow up visit with an average score of  $(4.0 \pm 0.0)$ . Finally, as regards to the total score of patients' level of adherence, it was noticed that two-fifths of the studied patients 60% had moderate level of adherence with an average score of  $(2.93\pm0.34)$ .

**Table (4)** presents percentage distribution of the studied patients according to their reasons of non-adherence to post HSCT regimen. It was observed that more than half of the studied patients, 56.3% had irregularity in their prescribed medications, the reasons were forgetfulness and financial limitations (25%, 20% respectively). Besides, exceeding three-quarters of the studied patients 76.3 % didn't adhere to dietary instructions, mainly due to economic reasons. Moreover, nearly half of the studied patients 52.5%, hadn't been advised to practice exercises.

While 100% of the studied patients thought that they were more susceptible to infection and that infection was dangerous for them.

**Table (5)** categorizes percentage distribution of the studied patients according to their current health status and associated complaints. Concerning current health status, the major percent of the studied subjects suffered from post HSCT complications, infections, and they weren't admitted to the hospital post HSCT with percentage of ( 92.5%, 71.3%, 73.8% respectively). As for their associated complaints, the highest percentage of the studied patients complained of abnormal skin color and itching, sores in lips or mouth, stomach complaint, spots on face, thinning of hair/loss, moon face, skin rashes, sensitivity to light and difficulty of vision/visual problems (51.3%, 51.3%, 51.3%, 51.3%, 60%, 53.8%, 53.8%, 51.3%, 51.3% respectively).

**Table (6)** reveals the percentage distribution of the studied patients according to the scores of laboratory investigations and vital signs. Most of the studied patients had normal result of RBCs, WBCs, hemoglobin, platelets, SGOT, SGPT, serum urea, serum creatinine and albumin ( 61.3%, 67.5%, 51.3%, 91.3%, 83.8%, 83.8%, 85%, 81.3% 97.5% respectively). While the result of C-reactive protein was abnormal in 100% of the studied patients. Regarding vital signs, almost all the patients had normal temperature, blood pressure, heart rate, and respiratory rate with percentage of ( 100%, 93.8%, 98.8% and 81.3% respectively).

**Table (7)** shows the percentage distribution of the studied patients according to their clinical outcomes' level and overall score. In relation to their current health status and associated complaints, the majority of the studied patients had poor clinical outcomes with percentages of (92.5%, 78.8% respectively). While the highest percent of them had good clinical outcomes considering their laboratory investigations and vital signs with percentages of (75%, and 98.8% respectively). Finally, their clinical outcomes overall score was poor for more than two-thirds (70%) of the studied patients.

**Table (8)** depicts the relation between patients' level of adherence and their clinical outcomes. Most of the studied patients with low and moderate level of adherence had poor outcomes (88.9%, 79.2% respectively). Moreover, most of the studied patients with high level of adherence had good clinical outcomes 56.5%, there was a statistically significant relation between patients' level of adherence and their clinical outcomes (p=0.004).

**Table (9)** shows the relation between patients' overall adherence level and their sociodemographic characteristics. There was a statistically significant relation between patients' overall adherence level and their age, sex and area of residence (p=0.004, 0.032, 0.016 respectively).

Patient's sociodemographic characteristics	No.	%
Age:		
• $20 - less than 30 years.$	14	17.5
• 30-less than 40 years.	36	45.0
• 40- less than 50 years.	23	28.8
• 50-60 years.	7	8.8
Sex:		
• Male.	48	60.0
• Female.	32	40.0
Educational level:		
• Illiterate.	16	20.0
• Read and write.	3	3.8
• Basic education.	6	7.5
• Secondary education.	38	47.5
• University education.	17	21.3
Marital status:		
• Single.	13	16.3
• Married.	64	80.0
• Widow.	3	3.8
Occupation:		
• Manual work.	33	41.3
• Employee.	15	18.8
• Housewife.	32	40.0
Area of residence:		
• Urban.	48	60.0
• Rural.	32	40.0
Economic status:		
• Enough.	25	31.3
• Not enough.	55	68.8

 Table (1): Percentage distribution of the studied patients according to their sociodemographic characteristics: (n = 80)

Table (2): Percentage distribution	of the studied	patients :	according	to their	clinical	data
	(n = 80)					

Patients clinical data	No.	%
Diagnosis:		
Hodgins's lymphoma.	9	11.3
• Leukemia.	71	88.8
Source of transplant:		
Autologous transplantation.	30	37.5
Allogeneic transplantation.	50	62.5
Time of transplantation:		
• $< 6$ months.	9	11.3
• 6 -12 months.	30	37.5
• $>12-24$ months.	5	6.3
• >24 months.	36	45.0
Associated chronic diseases: #		
• None.	50	62.5
• Hypertension.	5	6.3
• Hepatic disease.	5	6.3
Cardiac disease.	15	18.8
• Renal disease.	5	6.3
Current medications: #		
Antihypertensive drugs	5	6.3
Cardiac medication	15	18.8
Hepatic medication	5	6.3
Renal medication	5	6.3
Post transplantation	80	100.0

# More than one answer was selected.

Table (3): Percentage distribution of the studied patients according to their scores for level of adherence post
hematopoietic stem cell transplantation $(n = 80)$

Post hematopoietic stem cell transplantation	(Min. – Max.)	Total Score	Average Score	% Score	Lo (<5	ow 0%)	Mod (50 - •	erate <75%)	Hi (≥7:	igh 5%)
patients' level of adherence	Score	Mean ± SD.	Mean ± SD.	Mean ± SD.	No.	%	No.	%	No.	%
Adherence to the prescribed medication regimen.	(12 – 48)	$42.71 \pm 5.61$	$3.56\pm0.47$	85.31 ± 15.58	0	0.0	27	33.8	53	66.3
Adherence to the recommended diet.	(4 – 16)	$10.30\pm2.80$	$2.58\pm0.70$	$52.50\pm23.32$	41	51.3	29	36.3	10	12.5
Adherence to the prescribed physical activity and exercise.	(5 – 20)	$13.40 \pm 2.80$	$2.68\pm0.56$	$56.0 \pm 18.63$	19	23.8	51	63.8	10	12.5
Adherence to the precautions for infection prevention	(4 – 16)	$10.79\pm2.51$	$2.70\pm0.63$	$56.56\pm20.91$	32	40.0	19	23.8	29	36.3
Adherence to the recommended social activity precautions.	(5 – 20)	9.61 ± 1.91	$1.92\pm0.38$	30.75 ± 12.71	75	93.8	5	6.3	0	0.0
Adherence to the recommended medical follow up visits.	(1 – 4)	$4.0\pm0.0$	4.0 ± 0.0	$100.0\pm0.0$	0	0.0	0	0.0	80	100.0
Overall level of adherence	(31 – 124)	$90.81 \pm 10.48$	$2.93 \pm 0.34$	$64.31 \pm 11.27$	9	11.3	48	60.0	23	28.8

SD: Standard deviation

Table (4): Percentage	distribution	of the studied patie	ents according to	their reasons of
non- adherence to	post hematoj	poietic stem cell tra	nsplantation regi	men (n = 80)

Reasons of non-adherence to post hematopoietic stem cell transplantation regimen	No.	%
- Regularly having the prescribed medicines		
• Yes	45	56.3
• No	35	43.8
- Reasons for non-adherence to medications:		
• Forgetfulness.	20	25.0
• No desire to take medicines.	9	11.3
• Medication's side effects.	12	15.0
Medication causing troubles.	4	5.0
Financial limitations.	16	20.0
- Reasons to non-adherence to the dietary instructions:		
• Yes	61	76.3
• No	19	23.8
Economic reasons.	51	83.6
• Poor quality of the food described.	10	16.4
- Being advised to practice exercise:		
• Yes	22	27.5
• No	58	52.5
- Thinking of being more susceptible to infection than others:	0.0	100.0
• Yes	80	100.0
<ul> <li>Thinking that infection is dangerous for the nationt.</li> </ul>	U	0.00
<ul> <li>Yes</li> </ul>	80	100.0
• No	0	0.00

Table (5): Percentage distribution of the studied patients according to their current
health status and associated complaints post hematopoietic stem cell transplantation
(n = 80)

Current health status		es	No		
		%	No.	%	
1. Suffering from any post HSCT complications	74	92.5	6	7.5	
3. Suffering from any infection post HSCT	57	71.3	23	28.8	
5. Hospital admissions post HSCT	21	26.3	59	73.8	
Associated compleints post HSCT	Pre	sent		Absent	
Associated complaints post HSC I	No.	%	No.	%	
1. Abnormal skin color and itching.	41	51.3	39	48.8	
2. Mouth /lip sores.	41	51.3	39	48.8	
3. Stomach complaints.		71.3	23	28.8	
4. Tingling /numbness of hands.		38.8	49	61.3	
5. Hand tremors.		38.8	49	61.3	
6. Feeling of warmth in hands/feet.		38.8	49	61.3	
7. Dizziness		30.0	56	70.0	
8. Poor appetite	16	20.0	64	80.0	
9. Spots on face.	41	51.3	39	48.8	
10. Thinning of hair/loss.	48	60.0	32	40.0	
11. Moon face.	43	53.8	37	46.3	
12. Urgency.	23	28.8	57	71.3	
13. Skin rash.	43	53.8	37	46.3	
14. Sensitivity to light.	41	51.3	39	48.8	
15. Blurred vision .	41	51.3	39	48.8	

Table (6): Percentage distribution of the studied patients according to their scor	es of
laboratory investigations and vital signs: (n = 80)	

Scores of laboratory	M I CD	Abno	ormal	Normal		
investigations and vital signs	$Mean \pm SD.$	No.	%	No.	%	
Lab investigations:						
• RBCs	$4.06\pm0.55$	31	38.8	49	61.3	
• WBCs	$6.47 \pm 1.91$	26	32.5	54	67.5	
• Hemoglobin	$12.59 \pm 1.48$	39	48.8	41	51.3	
• Platelets	$276.9\pm104.1$	7	8.8	73	91.3	
• SGOT	$33.50\pm12.99$	13	16.3	67	83.8	
• SGPT	$38.53 \pm 14.19$	13	16.3	67	83.8	
• Serum urea	$31.08 \pm 12.94$	12	15.0	68	85.0	
• Serum creatinine	$1.17\pm1.19$	15	18.8	65	81.3	
• Albumin	$4.26\pm0.40$	2	2.5	78	97.5	
• CRP	$6.76\pm4.27$	80	100.0	0	0.0	
Vital signs:						
• Temp	$37.02\pm 0.13$	0	0.0	80	100.0	
Blood pressure		5	6.3	75	93.8	
✓ Systolic	$127.8\pm8.26$					
✓ Diastolic	$83.19\pm5.53$					
Heart rate	$78.24\pm5.80$	1	1.3	79	98.8	
Respiratory rate	$20.49 \pm 1.65$	15	18.8	65	81.3	

Patient's clinical	(Min. –	Total Score	Average Score	% Score	Poor (<70%)		Good (≥70%)	
outcome overall score	Max.) Score	Mean ± SD.	Mean ± SD.	Mean ± SD.	No.	%	No.	%
Current health status	(0-3)	$\begin{array}{c} 1.10 \pm \\ 0.88 \end{array}$	$\begin{array}{c} 0.37 \pm \\ 0.29 \end{array}$	$\begin{array}{r} 36.67 \pm \\ 29.34 \end{array}$	74	92.5	6	7.5
Associated complaints post HSCT	(0 - 15)	8.10 ± 3.15	$\begin{array}{c} 0.54 \pm \\ 0.21 \end{array}$	$54.0 \pm \\20.99$	63	78.8	17	21.3
Lab investigations	(0 - 10)	7.03 ± 1.42	$\begin{array}{c} 0.70 \pm \\ 0.14 \end{array}$	$70.25 \pm 14.23$	20	25.0	60	75.0
Vital signs	(0-4)	$\begin{array}{r} 3.49 \pm \\ 0.53 \end{array}$	$\begin{array}{c} 0.87 \pm \\ 0.13 \end{array}$	87.19± 13.19	1	1.3	79	98.8
Overall score	(0-32)	19.71 ± 4.04	$0.62 \pm 0.13$	61.60 ± 12.61	56	70.0	24	30.0

# Table (7): Percentage distribution of the studied patients according their clinical outcomes' level and overall score (n = 80)

Table (8): Relation between patients' level of adherence and their clinical outcomes (n = 80)

Level of adherence	(	Clinical (	χ <sup>2</sup>	Р		
	Poor (<70%) (n = 56)				Good (≥70%) (n = 24)	
	No.	%	No.	%		
Low (<50%)	8	88.9	1	11.1		
<b>Moderate</b> (50 <75%)	38	79.2	10	20.8	11.154*	0.004*
<b>High</b> (≥75%)	10	43.5	13	56.5		

χ<sup>2</sup>: Chi square test

\*: Statistically significant at  $p \le 0.05$ 

5001		( and a	ſ					
		Level						
Patient's	Low $(n = 9)$		Moderate (n		High (n =23)		$\chi^2$	Р
sociodemographic	No	0/	=4	10) 0/	No	0/		
A ===	INU.	70	INU.	70	INU.	70		
Age:	0	0.0	0	(1)	_	257		
20 - less than 30	0	0.0	9	64.3	5	35.7		MC
30-less than 40	5	13.9	18	50.0	13	36.1	$17.478^{*}$	$p = p^{\text{me}}$
40- less than 50	0	0.0	19	82.6	4	17.4	1,,0	0.004
50-60	4	57.1	2	28.6	1	14.3		
Sex:								
Male	9	18.8	27	56.3	12	25.0	6 868*	0.032*
Female	0	0.0	21	65.6	11	34.4	0.808	0.032
Educational level:								
Illiterate	5	31.3	7	43.8	4	25.0		
Read and write	0	0.0	3	100.0	0	0.0		MC
Basic education	1	16.7	4	66.7	1	16.7	11.245	p = 0.120
Secondary education	3	7.9	25	65.8	10	26.3		0.120
University education	0	0.0	9	52.9	8	47.1		
Marital status:	-		-			-		
Single	0	0.0	8	61.5	5	38.5		MC
Married	8	12.5	39	60.9	17	26.6	4.076	<sup>MC</sup> p=
Widow	1	33.3	1	33.3	1	33.3		0.329
Occupation:	-	00.0	-	0010	-	0010		
Manual work	6	18.2	18	54.5	9	27.3		
Employee	3	20.0	9	60.0	3	20.0	8.203	мср=
Housewife	0	0.0	21	65.6	11	34.4	0.205	0.074
Area of residence:	U	0.0	21	05.0	11	51.1		
Urban	9	18.8	24	50.0	15	313		
Rural	0	0.0	24	75.0	8	25.0	8.261*	0.016*
Feanamic status.	0	0.0	T	75.0	0	23.0		
Enough	3	12.0	14	56.0	8	32.0		
Not enough	6	12.0	3/	61.9	15	27.0	0.249	0.883
Not enough	0	10.9	54	01.8	13	21.3		

 Table (9): Relation between patients' level of overall adherence and their sociodemographic characteristics (n = 80)

 $\chi^2$ : Chi square test significant at  $p \le 0.05$ 

MC: Monte Carlo

\*: Statistically

#### **Discussion:**

Therapeutic regimen adherence in HSCT patients may be compromised by the complexity of their condition and could influence the clinical outcomes as well their survival. This calls for more understanding of their adherence pattern post-transplant; especially among adult patient. **Ibrahim and Shash (2022)** has declared that Egypt has the potential to become an eminent country in the field of oncology. Medical surgical nursing should have the research-based knowledge required to guide practice while caring for HSCT post-transplant patients which can be encountered during the planned outpatient visits or during incidental hospital readmissions. Thus, the current study aimed at identifying the relationship between adherence to therapeutic regimen and clinical outcomes among patients post HSCT; the study highlighted that two-fifths of the studied patients had moderate level of adherence to the therapeutic program, all of them were adhered in particular to the follow-up visits, more than two-thirds of them had poor clinical outcomes. Moreover, a statistically significant relation was found between patients' level of adherence and their clinical outcomes in addition to demographic characteristics namely; age, sex, and area of residence.

The socio-demographic findings of subjects revealed that the highest percent of them were less than 40 years, which comes in agreement with **El Afifi et al. (2016)** stated that the majority of their subjects were younger than 40 years. This might be attributed to the purposive candidate selection for transplant in this age group to be free of comorbid conditions, having physical and physiological fitness at the time of transplant.

Also, A higher percent of the studied subjects were males which is congruent with Smith et al. (2011) reported that hematological malignancies tend to occur more frequently in males, regarding this, Espinoza et al. (2016) interpreted the higher prevalence in males by the higher risk of exposure for hematologic malignancies' risk factors; smoking, benzene, pesticides -in term of the nature of their work – consequently this leads to DNA damage. Added to this, physiologic and genomic differences that might be relevant to the higher differential cancer susceptibility in males because females have higher immunologic functions (Dorak & Karpuzoglu, 2012).

Regarding education, secondary and university education was found in more than half of the present study subjects. This result agreed with that found by **Masala et al. (2012)** as around half of their subjects got high school education.

Moreover, nearly two- thirds of the studied patients live at urban regions. This result might be related to the long-distance patients from rural areas who should travel to have follow up care especially in the first 100 days after transplant. Egyptians from rural areas may have difficulties in transportation, and physicians at primary care services are not well informed for early detection of complications and the long distance from transplant center may be a barrier in dealing with these complications.

Regarding our subjects 'clinical data, leukemia was pretty high than Hodgkin's lymphoma which might be interpreted by the higher incidence of leukemia than other nonsolid cancer in Egypt as recently reported by Ibrahim and Shash (2022). Moreover, less than two-thirds of our subjects had allogeneic transplantation which might be interpreted by that most of the Egyptians have large families which reduces the difficulty of finding matched donors.

On the other hand, our findings revealed a wide range in the level of adherence related to the complexity of the therapy to the uncertainty and psychological distress experienced by the patients and their caregivers. Also, may be attributed to length of time post -transplantation, the results show, a statistically significant relation between patient's level of adherence and their diagnosis, source of transplant, time of transplantation. These results was supported by previous study that indicated medication non-adherence with a similar wide range among HSCT recipients **Gresch et al. (2017) & Morrison et al. (2017).** 

Despite the fairly high percent score of our subjects who reported adherence to medications with a high average score, those who reported irregularities in taking medications was not a few, they gave two main reasons which were forgetfulness and financial reasons, This finding can be explained **McGrady et al. (2016)** by that HSCT patients perceived that medications had more serious consequences on their disease and believed that treatment could control their cancer recurrence and vital for their lives.

More than two-thirds of the subjects reported that income was not enough. This low income as perceived by our subjects could explain that around one-fifth was highly adhered to the recommended dietary regimen, as it is a challenge in preparing the recommended diet. Besides, most of them lives in a family; either married or widowed which makes preparing food with specific consideration is very difficult among Egyptians patients in particular the two-fifths of them who came from rural areas where living in extended families is very common.

As for the infection prevention precautions, a high percent of our subjects had low level of adherence, although all of them thought that infection is dangerous, and they're more susceptible than others to catch infection, in addition, high percent of them catch infection post HSCT. In this regard, **Hashmi et al. (2017) reported that** a considerable proportion of patients found it challenging to comply with hygiene recommendations, even though treatment service was free, they added, the socio-economic burden and post-transplant follow-up period was further increased as strict home hygienic conditions are paramount. Also, less than two-thirds of the studied patients had moderate level of adherence to prescribed physical activity exercise. Slightly higher than one-tenth of our patients had highly adherence to practicing regular exercise which is explained by that they hadn't the information about its importance from physicians which was reported by nearly three-fifths of them.

Nearly all the studied patients had low level of adherence regarding recommended social activity precautions, this might be due to that nearly half of the subjects had their HSCT procedure since more than 24 months so strict adherence is no more required. As the religious beliefs and norms which emphasizes that visiting those who are sick, especially those in the close social system. Another finding was that all studied patients were highly adhered to follow up visit appointments, in this context, **Mahmoud et al. (2020)** have reported a follow-up dropout in nearly one-tenth of Egyptian patients, they further interpreted this by having most transplant units in the capital and major cities, while the vast majority of patients reside far away.

**Regarding overall level of adherence,** our study found that two-fifths of the studied patients had moderate level of adherence. This may be related to that nearly half of them had transplantation since more than 24 months, only around one-tenth had their HSCT in the previous six months before conducting the study. Concerning this, **McGrady et al. (2014)**, reported that adherence level has decreased from 91% during the first month to less than 60% after 6 months. Another factor among our population is the less prevalence of comorbidities and consequently less complex therapeutic regimen.

As for those non- adherent subjects in this study, the main reason for prescribed medications non-adherence was forgetfulness, although unexpected in such population as our middle adult subjects, it could be explained by the minority of them who were admitted to the hospital. Thus the majority of them didn't perceive neither susceptibility nor severity of complications, so they forgot timing, in addition to, the side effects of post HSCT medications and regimen complexity. Our finding could be interpreted by that mentioned by **Gresch et al. (2017)** as that patients were not prescribed identical medication which may have impacted adherence patterns, they added that barriers to adherence might be unintentional; as forgetfulness also, the belief that not all medications are necessary to prevent rejection . In this context, **Gresch et al. (2017)** reported a strong positive correlation between patients' GvHD symptoms and their medication non-adherence they also added

As regards the relation between adherence and the sociodemographic characteristic of our patients, there was statistical relation between marital status and the level adherence, the same result was found in **Zrinyi et al. (2003).** It is probably that women had more health awareness than men. Moreover, in the present study, highly educated patients had a higher level of adherence; this presumed that education level has a significant impact in adherence to therapy. Our results also showed that educational level affects the level of adherence.

Our study findings also revealed that most of the subjects had poor clinical outcomes as the majority suffered from post HSCT complications and complained of infection post HSCT. This may be due to non- adherence to precautions for infection prevention reported by most of them. Considering our patients' complaints from chronic GVHD, this may be attributed to irregularities in taking medications which was prevalent among nearly half of them, in this aspect, a study done by **Mumby et al. (2012)** found association between medication non-adherence in mostly autologous HSCT recipients and complaints; depression, distress, and nausea/vomiting.

Our results also showed that most of the studied patients had good clinical outcome regarding laboratory investigations such as RBCs, WBCs, platelets, urea, creatinine and vital signs. These results may be attributed to that most of them had HSCT since more than six months. Besides, statistically significant relation was found between patient's level of adherence and their clinical outcomes as most of the subjects with low and moderate adherence levels had poor outcomes. This is consistent with **Pai et al. (2018)** mentioned that poor adherence among patients with an allogeneic transplant is associated with increased incidence of infections during the outpatient treatment period. Concerning this, **Mistry et al. (2015)** reported that technology mediated adherence interventions revealed significant improvements in both adherence and clinical outcomes. Also, findings from randomized controlled trials in solid organ transplantation, there was positive statistical improvements in medication adherence, and general health outcomes (e.g., blood glucose or blood pressure) and overall quality of life **Schmid et al. (2017)**.

## **Conclusion:**

According to the results of the current study, it was found that all post HSCT patients were adhered to follow up visits, and most of them were highly adhered to the prescribed medication regimen, while they had low adherence as regards social activity precautions, infection prevention precautions, and the recommended diet. The majority of the studied patients had poor clinical outcomes. There is a statistically significant correlation between patient's level of adherence and their clinical outcomes, age, gender, in addition to residence.

## **Recommendation:**

Based on the results of the present study, the following recommendations are suggested:

- Routine adherence and clinical outcomes monitoring should be integrated into standard clinical care post-HSCT, to patients at risk for poor adherence; older adulthood, males, and those live in rural areas.
- Educational programs for HSCT patients should stress on teaching other aspects of therapeutic regimen and reinforce it every scheduled visit.
- Multidisciplinary health teams should be integrated in the outpatient follow-up visit as nurses, pharmacists, dietitians, physiotherapists, and social workers including primary centers in rural areas.
- Future studies should include larger samples to investigate the relation between nonadherence and its determinants and clinical outcomes.

• Finally, use cost effective, suitable tools for every patients' background to increase patients 'adherence post-HSCT, these tools may include but not limited to phone alarms, pill box, and telephone interviews.

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EJNHS Vol.4, No.2

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#### الملخص العربى

العلاقه بين الالتزام بالنظام العلاجى و النتائج السريريه بين المرضى بعد زراعه الخلايا الجذعيه

المقدمة: زرع الخلايا الجذعية المكونة للدم هو إجراء منقذ للحياة لحالات متعددة مثل السرطان، وإمراض المناعة، وامراض الدم. و قد يكون من الصعب الالتزام بالنظام العلاجي لدى مرضى زرع الخلايا الجذعيه بسبب تعقيد حالتهم وهو ما يمكن أن يؤثر على النتائج السريرية لهؤلاء المرضى، علاوة على ذلك، فإن عدم الالتزام يزيد من خطر الإصابة بنتائج صحية خطيرة مثل رفض الجسم للخلايا المنقوله ، أو العدوى، أو حتى الانتكاس و قد تؤدى ا جميع هذ المضاعفات إلى عودة المرض و فشل عمليه الزرع . **هدف الدراسة:** تهدف هذه الدراسة الى تحديد العلاقة بين الالتزام بالنظام العلاجي والنتائج السريرية بين المرضى بعد زراعة الخلايا الجذعية المكونة للدم. **نوع الدراسه**: هو تصميم البحث الارتباطي الوصفي. أجريت الدراسة في العيادة الخارجية لوحدة زراعة النخاع ، بمستشفى المواساة الجامعي، بمدينه الإسكندرية، مصر. عينه البحث : كانت تتألف من 80 مريضا بعد زراعه الخلايا الجذعيه ( HSCT) .أدوات البحث : تم استخدام ثلاث أدوات لجمع البيانات؛ الأداة الأولى: البيانات الاجتماعية و الديمو غر افية والسريرية لمرضى ما بعد زراعه الخلايا الجذعيه، استبيان المقابلة المنظم، الأداة الثانية: استبيان التزام مرضى زرع الخلايا الجذعية المكونة للدم. الأداة الثالثة: استمارة تقييم النتائج السريرية. النتائج: ثلثي المرضى الذين شملتهم الدر اسة (60٪) لديهم مستوى معتدل من الالتزام، وأكثر من ثلثيهم (70٪) لديهم نتائج سريرية سيئة، وكان هناك ارتباط ذو دلالة إحصائية بين مستوى التزام المريض وحالته السريرية. النتائج (ع = 0.004). الاستنتاج: أعلى نسبة من المرضى الذين شملتهم الدراسة كانوا ملتزمين بشدة بزيارات المتابعة ونظام الدواء الموصوف، في حين كانوا ملتزمين بشكل سيئ بالنظام الغذائي الموصبي به، واحتياطات الوقاية من العدوي، واحتياطات النشاط الاجتماعي. وكان معظم المرضى الذين شملتهم الدراسة نتائجهم السريريه سيئة. التوصية: يجب دمج الالتزام الروتيني ومراقبة النتائج السريرية في الرعاية السريرية القياسية لمرحلة ما بعد عمليه زرع الخلايا الجذعيه.