



## Effects of a Therapeutic Interventional Magic Solution in the Prevention of Oral Mucositis for Patients Undergoing Chemotherapy.

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### ABSTRACT

**Background:** The study aimed to demonstrate the effect of a magic solution on preventing oral mucositis in patients undergoing chemotherapy.

**Objectives:** The study aimed to focused on applying the magic solution as a potential treatment for prevention oral mucositis in cancer patients during chemotherapy.

**Methodology:** Study adopts pre- and post-testing as part of a quasi-experimental study design. The investigation was carried out at the Babylon Oncology Center between January 25 and May 17, 2023. Forty patients make up the study's sample, which was chosen using a non-probability sampling method. Experts validated the study instruments', and a pilot study was used to confirm the tools' dependability. Data were collected, and descriptive and inferential statistical analysis were used to analyze the data.

**Results:** The findings showed that 56.2 years old in the study group and 52.1 years old in the control were responders to the treatment. Sixty percent of participants were men. According to the study group's data, there was no noticeable difference in oral mucositis, severity, or toxicity between the two measurement periods known as the pre-test and post-test, which occurred before and after the intervention. The findings in the control group indicate a substantial difference in oral mucositis prevention, severity, and toxicity between two periods of measurements, such as a pre-test and a post-test (after the passage of seven days of taking the magic solution).

**Conclusion:** According to the results of the study, oral mucositis caused by chemotherapy can be avoided by using the magic solution. There were statistically significant differences between the study group and the control group, which indicates that the magic therapy was effective in avoiding inflammation of the oral mucosa. The intervention required additional research with a large sample size.

**Keywords:** Chemotherapy, Oral Mucositis, Magic Solution.

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## INTRODUCTION

Cancer is a global public health problem <sup>(1)</sup>. Cancer treatment including radiation therapy, chemotherapy, and combination therapies has a number of side effects that might cause difficulties <sup>(2, 3)</sup>. Inflammatory cytokines cause mucosal ulcerations, which enhanced the progression of a secondary infection <sup>(4)</sup>. Three to five days into the treatment cycle, the first symptoms of chemotherapy-induced mucositis start to appear, and they reach their peak seven to fourteen days later. Might be develops more than three weeks <sup>(5)</sup>. Oral mucositis is one of the most incapacitating side effects of cancer treatment. The condition known as oral mucositis, which is an inflammation of the mucous membrane accompanied by pain and ulceration, has a detrimental effect on quality of life <sup>(6)</sup>. Cancer treatment cycles must be delayed until the patient can tolerate additional cancer therapy and is healthy enough to eat and drink since oral mucositis may limit dosages and impact scheduling <sup>(7)</sup>. Oncology is gravely concerned about this morbid condition, which can occur anytime between 10% and 100% of the time depending on the cytotoxic treatment and patient-related variables <sup>(8)</sup>. Several models exist now that describe the progression of oral mucositis and offer suggestions for prevention <sup>(9)</sup>. Chlorohexidine-containing mouthwash has long been used to prevent oral mucositis and is one of the most promising treatments <sup>(10)</sup>, because it prevents fungus infections, nystatin is crucial in preventing the development of oral mucositis or the onset of grades III and IV <sup>(11)</sup>.

Mucositis brought on by cancer treatment may be prevented or reduced with the use of mouthwashes containing anti-inflammatory substances like doxycycline <sup>(12)</sup>. Glycerine is a safe, due to its hygroscopic nature, the colorless liquid has the ability to take in and store moisture from the environment. It is one of these affordable, natural products. When diluted to a concentration below 50%, it acts as a lubricant. Additionally, the combination of glycerin and water promotes flexibility and suppleness while preventing mucosal dryness <sup>(13)</sup>. Therefore, the study focused on applying the magic solution as a potential treatment for prevention oral mucositis in cancer patients during chemotherapy. The results of this study could be used to improve the post-chemotherapy patients' mouth health support swallowing, eating, and drinking.

## AIMS OF THE STUDY

The study Aimed to focused on applying the magic solution as a potential treatment for prevention oral mucositis in cancer patients during chemotherapy.

## METHODOLOGY

**Study Design:** Both the study and the control groups underwent pre- and post-testing as part of a quasi-experimental study design. was completed at the Babylon Oncology Center between January 25, 2023, and May 17, 2023.

**Study Sample:** The study sample for the current study, which consists of (40) chemotherapy patients, was chosen using a non-probability sampling approach based on a set of criteria that include: Patients who receive chemotherapy, patients who are

at least 18 years old, patients with diverse levels of education, and patients who consent to be included in the study sample are the first four criteria. The participants were split into two groups: group one (interventional group), which included 20 participants, used the magic solution protocol gargle every 6h. daily for seven days to prevent oral mucositis, while group two, which included 20 participants, served as the control group with no treatment.

**Study plan:** The sociodemographic data, such as age, gender, education level, occupation, smoking, chemotherapy type, duration, and chronic comorbidities.

The Cancer Institute of New South Wales (CINSW), created the second Oral Mucositis Assessment Tool in 2019. Because it was discovered in Britain, the researcher translated it as a back translation to check its accuracy and quality against the original text (We give the scale to a specialist who is fluent in the English and Arabic languages, in order to translate the scale from the original language into the Arabic language, and after that we give the Arabic translation (translation of the first specialist) of the scale, to another specialist translates it into the English language (i.e. to the original language), and we compare the translation in order to ensure its accuracy).

Oral Mucositis Assessment Tool has 13 domains. The sum of the final scores for each of them ranged from mild inflammation (13–20), moderate inflammation (21–26), and severe inflammation (27–39) and each of them included three elements as scoring levels. These 13 categories include: ability to sustain nutrition, analgesic needs, signs of infection, taste, voice, swallow, mucous membranes, saliva, tongue, lips, gums, teeth/dentures, and self-care assessment.

The third component of the oral toxicity scale was developed by the World Health Organization (WHO), which was established in 1979. There are five different grades of oral mucositis, with grade (0) being no symptoms and a normal diet, level (1) being soreness with/without erythema and the ability to eat solids, grade (2) being erythema and ulcers and the ability to eat soft or liquid diets, grade (3) being confluent ulcerations with/without exudates, and grade (4) being deep ulcerations and/or necrosis and the inability to eat by mouth.

Additionally, the King's College London Dental Institute, under the direction of Professor Stephen Challacombe, developed the Challacombe scale for oral dryness.

**Data Collection:** The researcher conducted interviews with the participants, gave them a copy of the questionnaire, answered their questions about it and also for the demographic characteristics, persuaded them to participate, and expressed gratitude for their participation. The interviewing method was utilized in the data collection process. After taking the crucial actions that must be considered in the study design, the researcher and the oncologist supervisor measured the oral toxicity and documented them in the study instrument. Each interview was conducted 20–25 minutes afterwards.

**Statistical Analysis:** All of the analyses were performed using the IBM SPSS 24 program. The variables were classified using numbers and percentages (No. and%), and the continuous variables (mean and SD) were described using the mean and standard deviation. Applying the period t-test and post hoc tests, one group was examined for changes between pre- and post-test results. A two-tailed p.05 was used to indicate statistical significance.

**RESULTS:****Table (1): Socio-demographic characteristics of study sample**

SDVs	Classification	Study		Control		Chi. Sig.
		No.	%	No.	%	
Age/years	<40 years old	2	10.0	4	20.0	7.197
	40-49 years old	4	20.0	4	20.0	.543
	50-59 years old	6	30.0	8	40.0	
	60 and older	8	40.0	4	20.0	
	<b><i>M± SD</i></b>	<b>56.2 ± 12.93</b>	<b>52.1 ± 11.62</b>			
Gender	Male	12	60.0	8	40.0	.278
	Female	8	40.0	12	60.0	.589
Education Level	Illiterate	2	10.0	2	10.0	30.278
	Read and write	4	20.0	4	20.0	.214
	Elementary school	6	30.0	2	10.0	
	Middle school	4	20.0	2	10.0	
	High school	2	10.0	6	30.0	
	College	2	10.0	4	20.0	
	Occupation	Unemployment	12	60.0	10	50.0
Free-business		2	10.0	8	40.0	.809
Employee		2	10.0	2	10.0	
Retired		4	20.0	0	0.0	
Smoking	Smoker	4	20.0	6	30.0	6.667
	Previous smoker	6	30.0	2	10.0	.155
	Non smoker	10	50.0	12	60.0	

The average age of the study group's patients was 56.2 years, compared to 52.1 years for the control group's patients. There were no statistically significant differences between the study group's (30%) and the control group's (40%) averaged between 50-59 years. With 60% of the sample being male in the study group and 60% being female in the control group, there was no gender difference between the groups. In terms of educational level, 30% of research group participants were in elementary school, whereas 30% of control group participants were in high school. The unemployment rate in the study and control groups was (60% and 50%, respectively). In terms of smoking, there were no differences between the study and control groups' percentages of non-smokers (50% and 60%, respectively).

**Table (2): Prevention of oral mucositis among patient undergo ct in study and control groups**

Groups	Class	Pre-test			Post-test		
		No.	%	<i>M ± SD</i>	No.	%	<i>M ± SD</i>
Study Group	Mild (13-20)	20	100.0	13.7 ± 0.92	18	90.0	14.5 ± 2.43
	Moderate (21-26)	0	0.00		2	10.0	
	Sever (27-39)	0	0.00		0	0.00	
Control Group	Mild (13-20)	20	100.0	13.7 ± 1.05	8	40.0	21.3 ± 4.62
	Moderate (21-26)	0	0.00		8	40.0	
	Sever (27-39)	0	0.00		4	20.0	

The distribution of patients receiving CT in accordance with the study group's pre- and post-intervention use of magic solution to prevent oral mucositis. Results show that (100%) of patients had minor oral mucositis prior to

receiving the magic solution treatment, which was 13.7 ( 0.90). While results from the post-test, which was conducted seven days after the magic solution's treatment, show that 90% of patients had minor disease ( $14.5 \pm 2.43$ ).

The distribution of patients receiving CT in the control group (100%) at the pre- and (40%) for mild and moderate respectively ( $21/3 \pm 2.43$ ) at post-test without the use of magic solution in order to prevent oral mucositis. Findings show that during the pre-test, 13.7 (1.05), 100% of patients had mild oral mucositis. While results from the post-test (after seven days) show that 40% of patients had mild to moderate oral mucositis.

**Table (3):** Difference in prevention of oral mucositis between pre and post-test study and control groups

Oral Mucositis	Periods	M	SD	t-value	d.f	Sig.
Study Group	Pre-test	1.05	.072	1.598	19	<b>.126</b>
	Post-test	1.12	.192			
Control Group	Pre-test	1.05	.081	7.843	19	<b>.000</b>
	Post-test	<b>1.64</b>	<b>.112</b>			

The results show that there was no statistically significant difference in the level of oral mucositis between the pre-test (M=1.05) and post-test (M=1.12) periods of measurements for the study group ( $t = 1.598$ ;  $p = .126$ ). The outcomes for the control group show a statistically significant difference in oral mucositis prevention between the pre-test (M=1.05) and the post-test (M=1.64), which were completed after the passage of seven days ( $t = 7.843$ ;  $p = .000$ ).

**Table (4):** Prevention of oral toxicity among patient undergo ct in study and control groups

Groups	Grade	Pre-test			Post-test		
		No.	%	<i>M ± SD</i>	No.	%	<i>M ± SD</i>
Study Group	0	20	100.0	$1.00 \pm 0.00$	18	90.0	$1.1 \pm 0.316$
	I	0	0.0		2	10.0	
	II	0	0.0		0	0.0	
	III	0	0.0		0	0.0	
	IV	0	0.0		0	0.0	
Control Group	0	20	100.0	$1.00 \pm 0.00$	10	50.0	$1.60 \pm 0.699$
	I	0	0.0		8	40.0	
	II	0	0.0		2	10.0	
	III	0	0.0		0	0.0	
	IV	0	0.0		0	0.0	

Results reveal that all patients (100%) were in grade 0 (0.00) prior to receiving the magic solution intervention. While data indicate that after using magic solution for seven days, 90% of patients experienced grade 0 oral toxicity at the post-test. Pre-test results revealed grade 0 oral toxicity in 100% of patients, while post-test findings revealed grade 0 oral toxicity in 50% of patients after seven days. The distribution of patients undergoing CT in the control group at the pre- and posttest without employing magic solution in order to prevent oral toxicity.

**Table (5):** Difference in prevention of oral toxicity between pre and post-test study and control groups

Oral Toxicity	Periods	M	SD	t-value	d.f	Sig.
Study Group	Pre-test	1.00	.000	1.453	19	.163
	Post-test	1.10	.316			
Control Group	Pre-test	1.00	.000	3.943	19	.001
	Post-test	1.60	.699			

Results for the study group indicate that there was no statistically significant difference in the prevention of oral toxicity between the pre-test (M=1.00) and post-test (M=1.10) periods of measurements ( $t = 1.453$ ;  $p = .163$ ). Results for the control group indicate a significant difference in oral toxicity prevention between pre-test (M= 1.00) and post-test (M=1.60) measurements (after the seven-day time) ( $t = 3.943$ ;  $p = .001$ ).

**Table (6):** Prevention of oral dryness among patient undergo ct in study and control groups

Groups	Class	Pre-test			Post-test		
		No.	%	M ± SD	No.	%	M ± SD
Study Group	Mild (1-3)	20	100.0	1.00 ± 0.00	16	80.0	1.30 ± 0.67
	Moderate (4-6)	0	0.0		2	10.0	
	Sever (7-10)	0	0.0		2	10.0	
Control Group	Mild (1-3)	20	100.0	1.00 ± 0.00	12	60.0	1.50 ± 0.70
	Moderate (4-6)	0	0.0		6	30.0	
	Sever (7-10)	0	0.0		2	10.0	

The results show that (100%) of patients had mild mouth dryness prior to using the magic solution intervention, which was 1.00 ( 0.00). While, at the post test following the use of the magic solution for seven days, results show that (80%) of patients had mild mouth dryness, 1.30±0.67. Results show that the control group during the pre-test, 1.00 ( 0.00), 100% of them had minor mouth dryness. While results show that 60% of patients had minor mouth dryness (after seven days), 1.50 ( 0.70).

**Table (7):** Difference in prevention of oral dryness between pre and post-test study and control groups

Oral Dryness	Periods	M	SD	t-value	d.f	Sig.
Study Group	Pre-test	1.00	.000	1.406	19	.139
	Post-test	1.30	.674			
Control Group	Pre-test	1.00	.000	3.249	19	.004
	Post-test	1.50	.707			

According to the results for the study group, there was no statistically significant change in the avoidance of mouth dryness between the pre-test (M=1.00) and post-test (M=1.30) measurement periods ( $t = 1.406$ ;  $p = .139$ ). In the control group, pre-test M= 1.00 and post-test M= 1.50 measurements after seven days show a statistically significant difference in oral dryness prevention ( $t = 3.249$ ;  $p = .004$ ).

## DISCUSSION

In terms of participant characteristics, the study and control groups' mean ages are 56.2 12.93 and 52.1 11.62, respectively; 60% of them is a male at the study group, while 60 of them are a female. For the study group, the percentage of participants who are

60 years or older is (40%), while (40%) for the age 50 to 59 at the control group. These findings are in line with those of study that expressed how side effects and problems from cancer treatment can manifest into old age <sup>(14)</sup>, also, this is supported by research

from Brazil, which revealed that study participants were, on average, 48 years old or older <sup>(15)</sup>.

In the initial measurement, the mean oral mucositis scores for the study group and the control group were 13.7 0.92 and 13.7 1.05, respectively. The control group's mean score increased to 21.3 4.62 at the second measurement, while the study group's mean score was 14.5 2.43. These findings imply that the use of a magic treatment may be useful in protecting CT patients against oral mucositis.

The randomized controlled clinical trial was conducted in an Iranian cancer hospital using aloe vera and chamomile gel. To the control group was administered a placebo gel. This shows that oral mucositis in the study group was less frequent and less severe than in the control group <sup>(16)</sup>. In a different study, conducted in Egypt, three groups received topical anesthetic, anti-inflammatory, and antifungal treatments three times per day for three weeks. Group II received 3% chamomile topical oral gel, and group III received both conventional symptomatic treatment and chamomile topical oral gel. The outcomes of this study demonstrate that topical chamomile 3% gel can lessen the discomfort experienced by the other two groups while reducing the degree of mucositis <sup>(17)</sup>. Additionally, in the post-test phase, the mean oral mucositis score of the control group was significantly greater than that of the group using aloe vera mouthwash <sup>(18)</sup>.

According to the study's findings, both groups experienced no oral toxicity following CT, with the Study Group seeing a lower incidence of oral mucositis than the Control Group. A total of 20 study and 20 control, the study group experienced 10% Grade I oral toxicity, compared to 40% Grade I oral toxicity and 10% Grade II oral toxicity in the Control Group. These findings imply that the administration of the magic solution may protect patients undergoing CT from oral toxicity.

It is clear from the results that the study and control groups' mean values for the oral toxicity durations varied between the pre-test and post-test

measures. The mean value of the oral toxicity period in the study group increased somewhat from 1.00 to 1.10, with a standard deviation of 0.316. In contrast, the mean value of the oral toxicity period increased more dramatically in the control group, from 1.00 to 1.60, with a standard deviation of 0.699.

The t-value for the difference between the two measurements, which was 3.943, revealed that there was a statistically significant difference between the pre- and post-test measures in the control group ( $p=0.001$ ). The t-value for the study group's pre- and post-test showing differences, indicating that there was no statistically significant difference between the two assessments ( $p=0.163$ ). In comparison to the control group, the use of magic solution—was successful in preventing or reducing the occurrence of oral toxicity. However, it is crucial to remember that other factors, such as variations in the types or doses of chemotherapy the patients received, which were not controlled for in this study, may have had an impact on the difference between the study and control groups.

A study carried out in Italy using the mouthwash Remargin Colostrum showed that the experimental technique seemed efficient in reducing severe types of oral toxicity <sup>(19)</sup>. In another study in Egypt using 3% chamomile topical oral gel showed that it might reduce the toxicity of mucositis while causing less discomfort than the other two groups <sup>(20)</sup>. The oral glutamine may not have any clinical benefits to prevent or lessen the incidence and severity of radiation-induced OM in patients with HNC receiving irradiation alone or in parallel with chemotherapy, according to a study from China. Furthermore, it is unknown if oral glutamine can postpone the onset of oral toxicity <sup>(21)</sup>. A study done in Iran further supported the fact that the patients were given two preventative regimens: regimen 1 contains amphotericin B, nystatin, chlorhexidine, and povidone iodine. Regimen 2 included povidone iodine and nystatin. This study found that adding amphotericin B and chlorhexidine to nystatin and povidone iodine

significantly improved the probability of preventing OM (22).

For chemotherapy patients, avoiding mouth dryness is essential because it can negatively impact their well-being. In this study, a study group and a control group were used to compare the efficacy of a magic remedy in avoiding oral dryness in chemotherapy patients. The findings revealed that the magic remedy was successful in reducing mouth dryness because the study group had a lower incidence than the control group.

The study comprised patients with mild (1-3), moderate (4-6), and severe (7-10) occurrences of oral dryness. In both the study and control groups, all patients had pre-test scores of 1.00 0.00, indicating that there was no mouth dryness at baseline. However, at the post-test, the percentage of patients in the study group was higher (80% vs. 60%, respectively) than in the control group, while the proportion of patients with moderate and severe oral dryness was lower (both 10%, vs. 30% and 10%, respectively) in the control group. The mean score for the study group was also lower (1.30 0.67) than the mean score for the control group (1.50 0.70).

The study group's mean oral dryness score was 1.00 prior to the use of the magic solution, but it climbed to 1.30 following the intervention, according to the data. On the other hand, the control group's mean oral dryness score increased from 1.00 before the intervention to 1.50 after the same time taken for the study group. The mean scores for both groups were compared between the pre-test and post-test periods using a t-test technique. The findings demonstrated that at the post-test period, the study group's mean score was considerably lower than the control group's ( $t=1.406$ ;  $p=.139$ ). Similar to this, the t-test analysis revealed that the control group's mean score during the post-test period was substantially higher than the study group's ( $t=3.246$ ;  $p.004$ ).

These results imply that the magic remedy was successful in avoiding mouth dryness in chemotherapy patients. Comparatively to the control

group, the study group had mouth dryness less frequently and to a lesser extent. The study had a limited sample size, and other variables, such as the patients' underlying medical conditions and medication use, may have influenced the findings, so it is crucial to stress that additional research is required to validate these results. Overall, the study supports the use of topical and systemic medicines in chemotherapy patients to avoid oral mucositis, but it also highlights the need for customized preventive and management strategies (23).

The significant difference between the post-test study and control groups, which is corroborated by research from Turkey, implies that eating sugar-free gum can help reduce mouth dryness. To support these findings, additional research with bigger sample sizes and appropriate multiple comparisons adjustment is required (24). Additionally, the herbal remedy with extracts of sage, chamomile, and green tea was superior to a placebo in terms of reducing mouth dryness, and there was a statistically significant difference between the study and control groups (25).

## CONCLUSION

According to the results of the study, oral mucositis caused by chemotherapy can be avoided by using the magic solution. There were statistically significant differences between the study group and the control group, which indicates that the magic therapy was effective in avoiding inflammation of the oral mucosa. The intervention required additional research with a large sample size.

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