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RESEARCH ARTICLE

IMMUNE MODULATING DRUGS USED IN SKIN DISEASE AND MOST BOTHERING SIDE EFFECTS

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Abstract

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Introduction:-

A substance that stimulates or suppresses the immune system and may help the body fight cancer, infection, or other diseases. Specific immunomodulating agents, such as monoclonal antibodies, cytokines, and vaccines, affect specific parts of the immune system. (National Cancer Institute, 2019)

The immunomodulating drugs commonly used in dermatology include:

Methotrexate, Azathioprine, Cyclosporin. (Oakley, 2016) These drugs are widely used in the treatment of skin conditions, which constitutes their importance and the importance of recognizing the success rate.

Rationale:

For any topic talking about drugs used in skin conditions, this is of great importance to the patient because most of the therapeutic drugs may affect the reduction of bad appearance such as eczema for example in the hands which means that this is important in the attention to the external form, As well as the psychological state as it is said when one is beautiful and good-looking, his psychological state will be comfortable and better than anyone else.

This research will show the success rate of these drugs in skin conditions, which will help in the evaluation of drugs based on the opinions of patients used.

Literature review:

According to the other previous study like:

This study:

Methotrexate use in allergic contact dermatitis: a retrospective study. (Patel A, 2017)

the objective was: To evaluate the efficacy and tolerability of methotrexate in treating allergic contact dermatitis, and the result was: Seventy-eight per cent (25/32) of patients showed either a partial or a complete response. (Patel A, 2017)

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This is mean this study was a good study Consistent with the accuracy of the figures used in this research, this is logically and computationally consistent with the way the analyst adheres to the data accurately.

Another study: Comparative Safety of Systemic Immuno-modulatory Medications in Adults with Atopic Dermatitis. (Schneeweiss MC, 2019)

The objective was: evaluated the comparative risk of serious bacterial and opportunistic infections among users of systemic immuno-modulatory medications in patients with severe AD in routine care, and the result was: The incidence of serious infections was 7.53 per 1,000 (7.18-7.89) among systemic non-biologics and 7.38 per 1,000 (5.68-9.57) among phototherapy treated patients, and 2.6 per 1,000 (0.45-14.3) dupilumab users. (Schneeweiss MC, 2019)

But on the other hand the mechanism used in the research in terms of comprehensiveness was superfluous, which leads to dispersion and lack of clarity, there are many drugs that fall under the title immune-modulatory drugs These medications may be a bit similar in the way they work inside the body, but in simplified terms the bodies are not similar in reaction to each drug, This was never evident in this research

Research Aim:

to determine the percentage success of immune-modulating drugs used in skin disease and most bothering side effects.

Objectives:-

1. To determine how many people used one of the immune-modulating drugs.
2. To study the relationship between the duration of drug use and the appearance of complications
3. To identify the most common complications.
4. The extent of the patient's evaluation of the drug used.

Methodology:-

Study design:

This is an analytical cross-sectional study.

Study Setting and period:

This is an analytical cross-sectional study conducted in kingdom of saudia Arabia (Outpatient and in patient.), from 1/4/2019 till 19/10/2019.

Study population and sampling:

Study participants, Inclusion criteria:

patient used immune-modulating drugs criteria; patient unused Non immune-modulating drugs.

Sampling Method:-

The study will be carried out by questionnaire.

Sampling size:

Sample size was calculated using OpenEpi for sample size calculation for cross sectional studies, hypothesizing the true answers Accordingly, **530** participants were gathered from the hospital patients. 78.68% of the respondents are females. The results showed that the majority of respondents did not use these drugs 88.30%, The results indicated that most respondents say that thary give the success of the medication more than 5 from 10. prevalence of who do not face any side effects 87.36%.

According to the prevalence study, the results indicated that most respondents who use the drugs use it for hand dermatitis 1.89%. the respondents distributed their responses almost equally to the drugs, the majority of them answered that the duration is from 7-10 days.

Measurements:-

Explanatory variables:

1. Sociodemographic characteristics: gender, age, nationality.

2. Disease-related information: used of medication, name of medication, duration, side effects, indication, success of the medication .

Outcome Measures:-

The outcome measure is by counting the ratio of the number of patients have used immune-modulating drugs in skin disease this will be measured using:

By determining the extent of the success and side effects associated with used of immune-modulating drugs in skin disease.

Prevalence study: will be carried to test the questionnaire if easily understood and the response of the participants. Data from the cross-sectional study will be used to calculate the sample size.

Data Management and Analysis plan:

Data will be entered and analyzed using SPSS version 17.0 Descriptive statistics will be performed and categorical data will be displayed as frequencies and percentages while measures of central tendencies and measures and dispersion will be used to summarize continuous variables. Univariate and multivariate analysis will be performed to investigate association between exposure factors and associated disease. statistical significance is set at a P value of 0.05 or less.

Statistical analysis

Data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 17. Descriptive statistics were displayed as frequencies and percentages for categorical variables. Measures of central tendencies (the median), and measures and dispersion (minimum – maximum) were used to summarize continuous variables, as the continuous variables were not normally distributed when tested by Shapiro-Wilk test. Univariate analysis was performed to investigate the association between the exposure factors with the outcome on the one hand, this was performed using Chi-squared test and Mann-Whitney test. Multivariate analysis to investigate factors independently was performed using binary logistic regression. P value was set at a significance level of < 0.05.

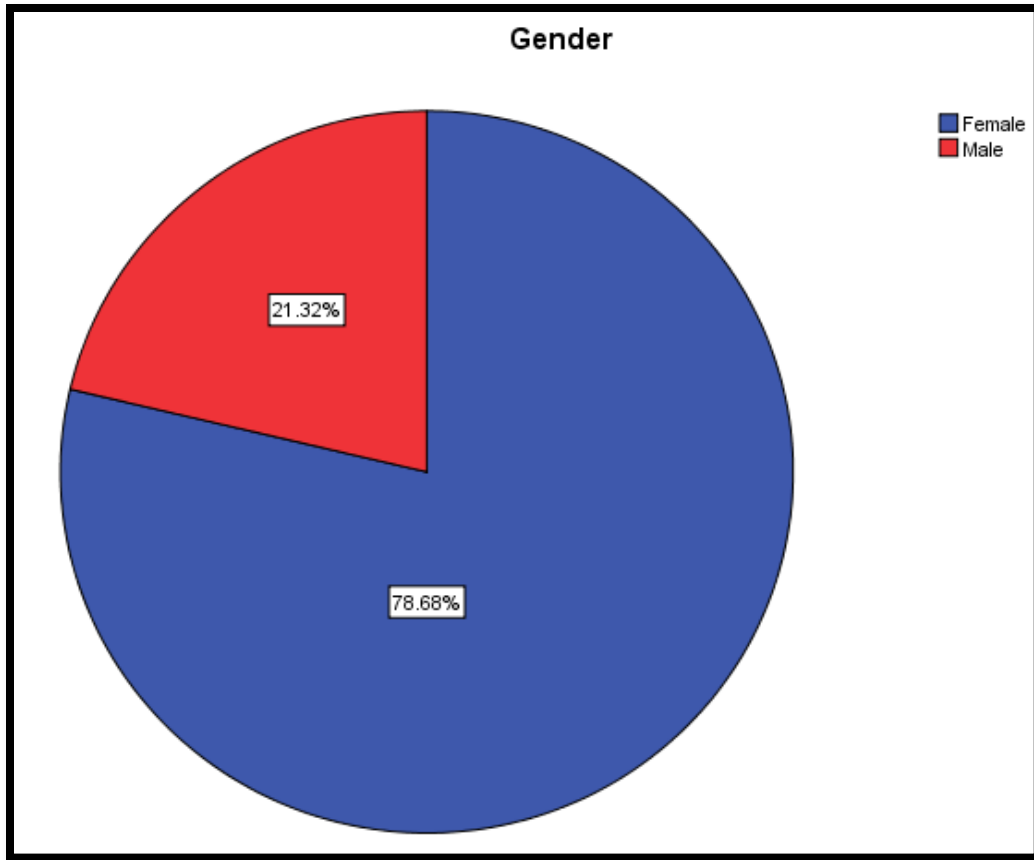
Results:-

In this study, the aim was to determine the percentage success of immune-modulating drugs used in skin disease and most bothering side effects. , 530 patients' participants, were consecutively recruited from in patients' clinics, during a period from 1/4/2019 to 19/10/2019

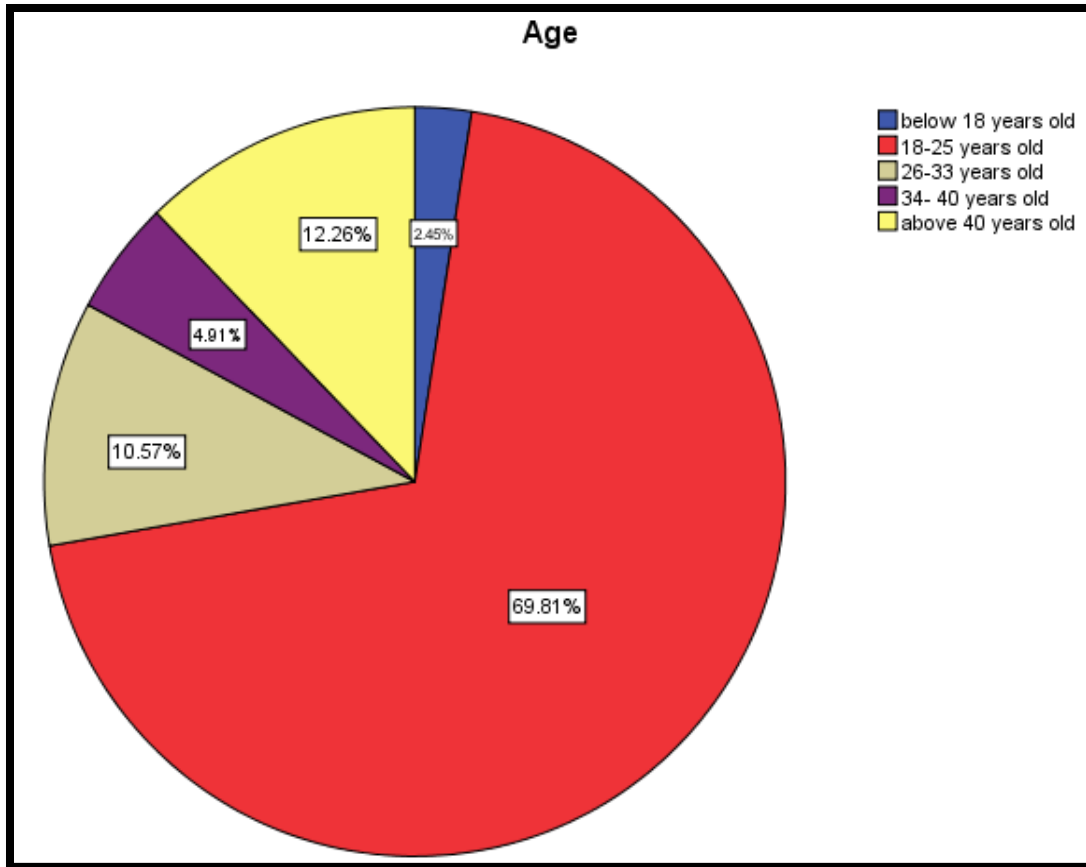
According to drugs 88.30% of respondents did not use these drugs, The results indicated that most respondents say that they give the success of the medication more than 5 from 10. prevalence of who do not face any side effects 87.36%.

Frequency Table:-

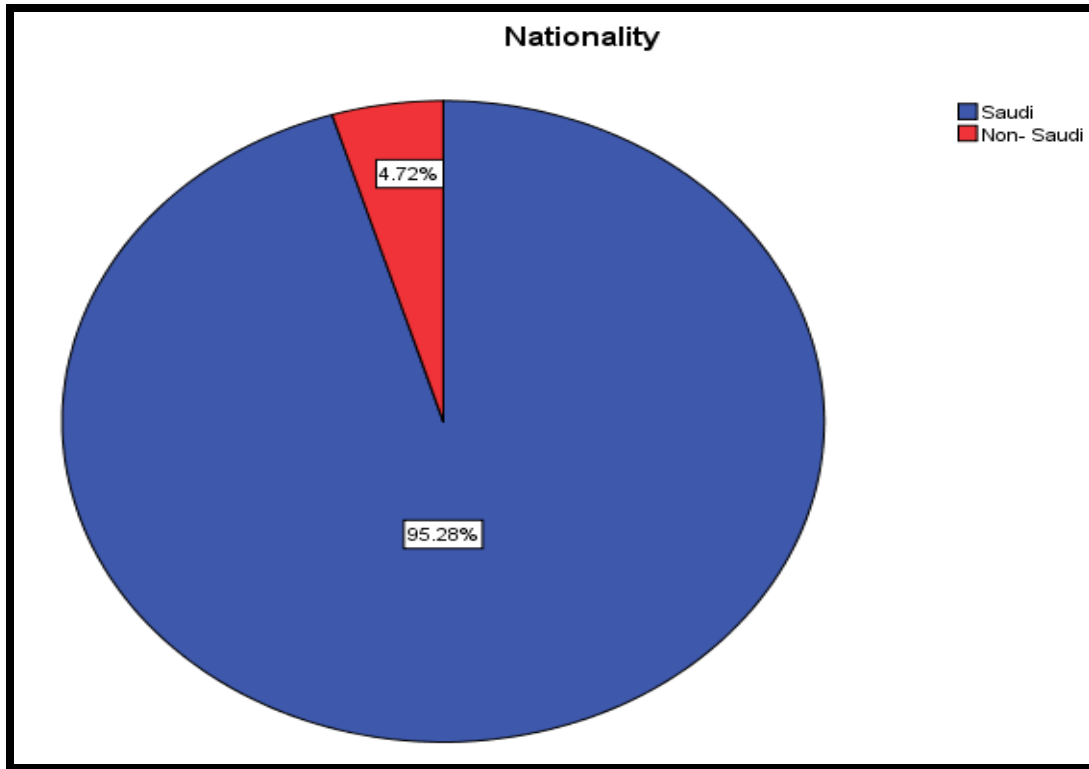
Gender					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Female	417	78.7	78.7	78.7
	Male	113	21.3	21.3	100.0
	Total	530	100.0	100.0	



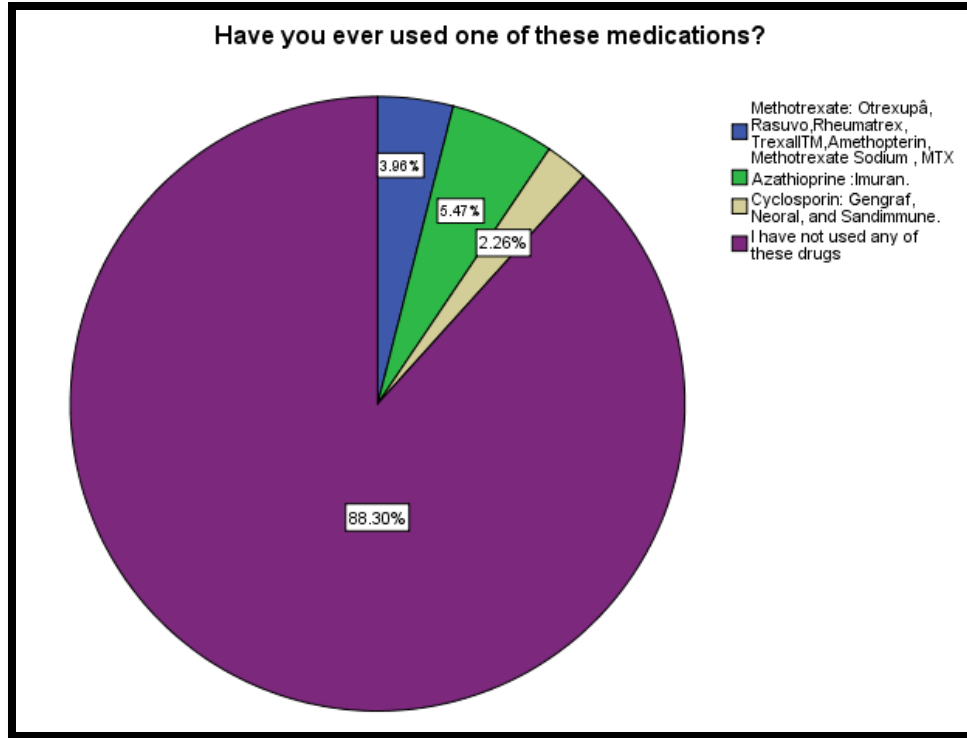
Age					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	below 18 years old	13	2.5	2.5	2.5
	18-25 years old	370	69.8	69.8	72.3
	26-33 years old	56	10.6	10.6	82.8
	34- 40 years old	26	4.9	4.9	87.7
	above 40 years old	65	12.3	12.3	100.0
	Total	530	100.0	100.0	



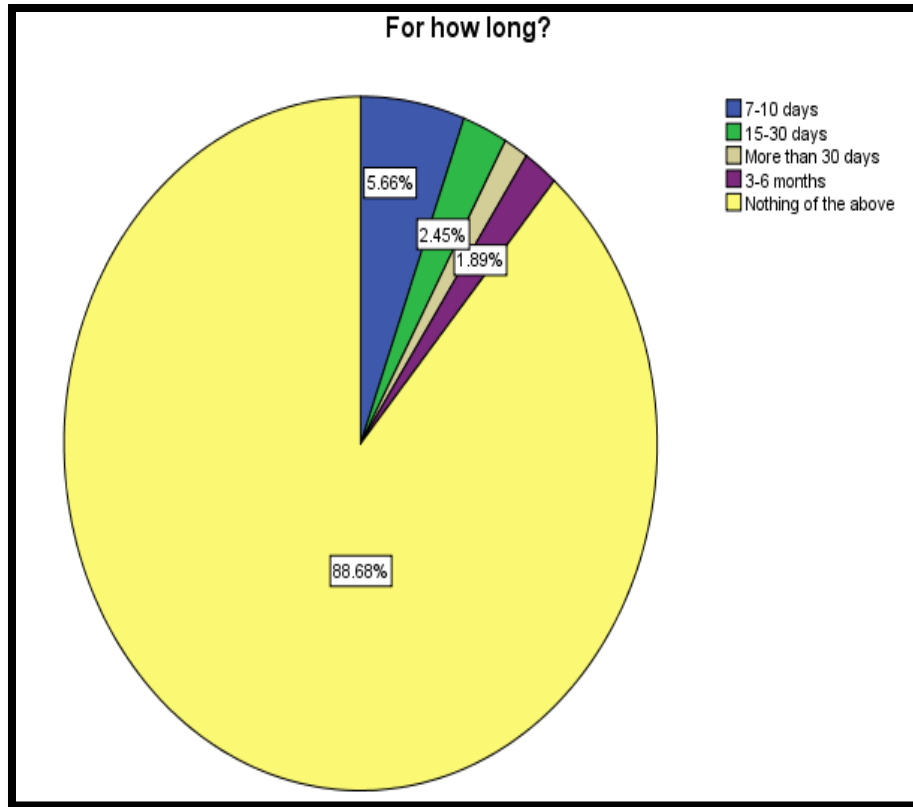
Nationality					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Saudi	505	95.3	95.3	95.3
	Non- Saudi	25	4.7	4.7	100.0
	Total	530	100.0	100.0	



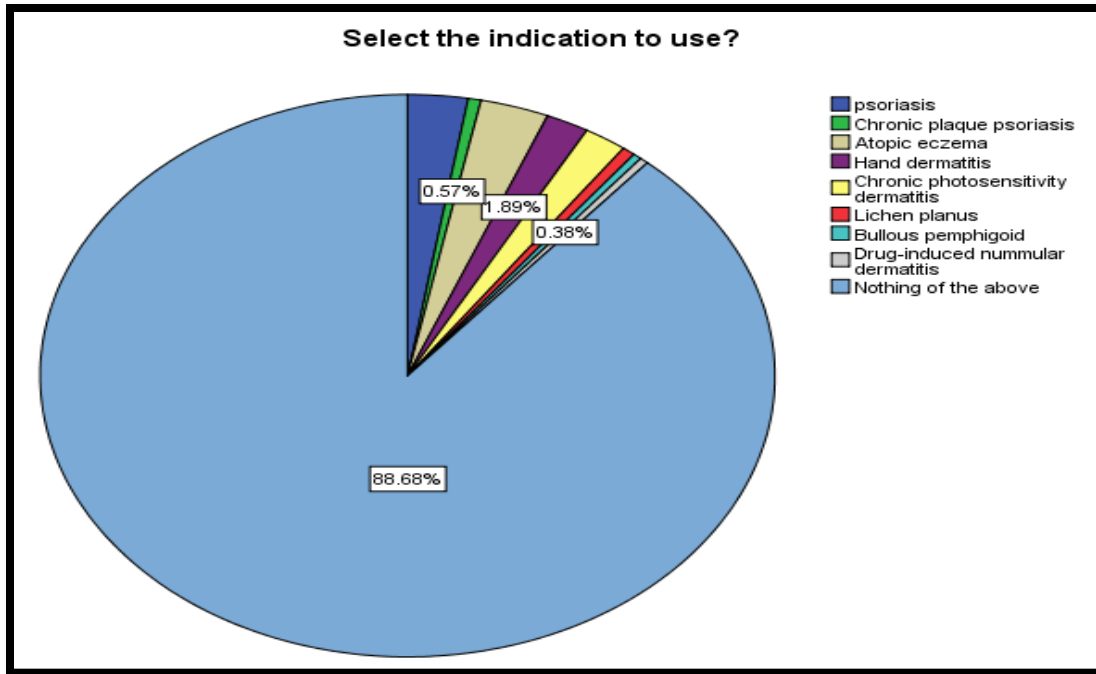
Have you ever used one of these medications?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Methotrexate: Otrexupâ, Rasuvo, Rheumatrex, TrexallTM, Amethopterin, Methotrexate Sodium , MTX	21	4.0	4.0	4.0
	Azathioprine :Imuran.	29	5.5	5.5	9.4
	Cyclosporin: Gengraf, Neoral, and Sandimmune.	12	2.3	2.3	11.7
	I have not used any of these drugs	468	88.3	88.3	100.0
	Total	530	100.0	100.0	



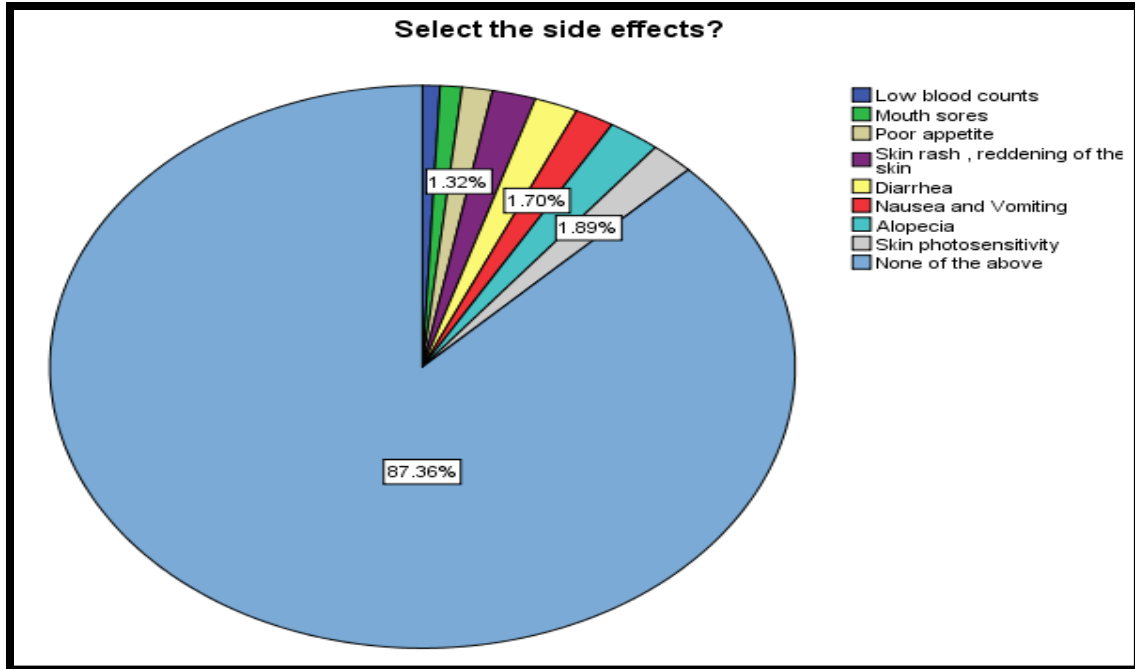
For how long?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	7-10 days	30	5.7	5.7	5.7
	15-30 days	13	2.5	2.5	8.1
	More than 30 days	7	1.3	1.3	9.4
	3-6 months	10	1.9	1.9	11.3
	Nothing of the above	470	88.7	88.7	100.0
	Total	530	100.0	100.0	



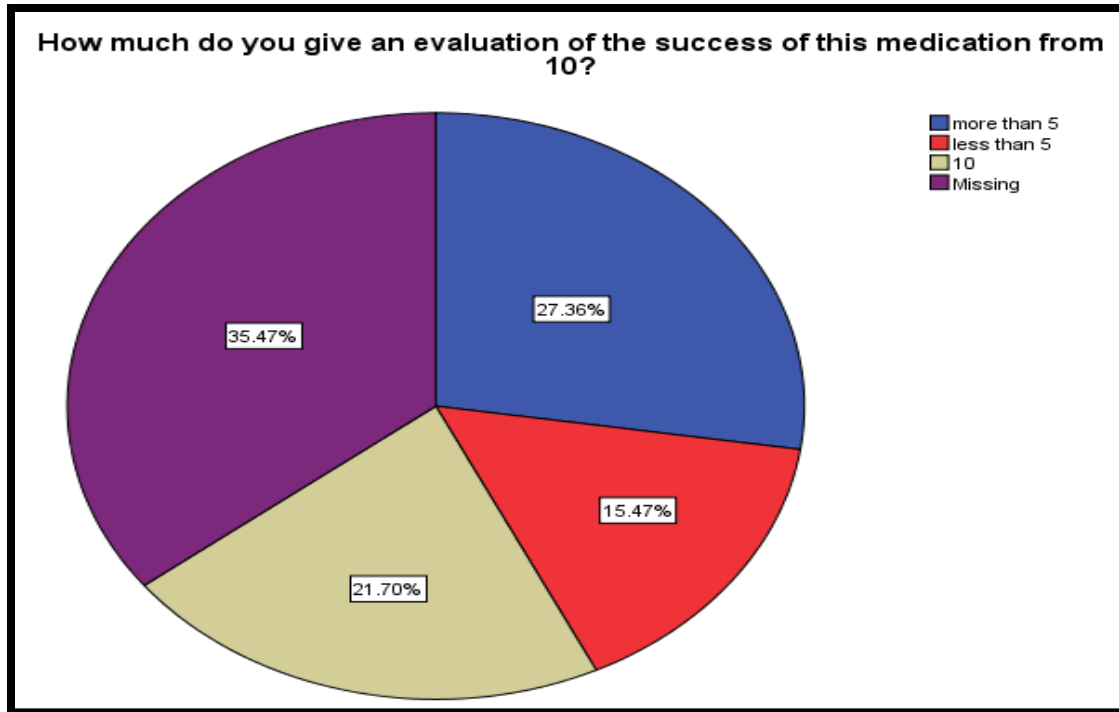
Select the indication to use?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Psoriasis	14	2.6	2.6	2.6
	Chronic plaque psoriasis	3	.6	.6	3.2
	Atopic eczema	16	3.0	3.0	6.2
	Hand dermatitis	10	1.9	1.9	8.1
	Chronic photosensitivity dermatitis	10	1.9	1.9	10.0
	Lichen planus	3	.6	.6	10.6
	Bullous pemphigoid	2	.4	.4	10.9
	Drug-induced nummular dermatitis	2	.4	.4	11.3
	Nothing of the above	470	88.7	88.7	100.0
Total	530	100.0	100.0		



Select the side effects?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Low blood counts	4	.8	.8	.8
	Mouth sores	5	.9	.9	1.7
	Poor appetite	7	1.3	1.3	3.0
	Skin rash , reddening of the skin	10	1.9	1.9	4.9
	Diarrhea	10	1.9	1.9	6.8
	Nausea and Vomiting	9	1.7	1.7	8.5
	Alopecia	12	2.3	2.3	10.8
	Skin photosensitivity	10	1.9	1.9	12.6
	None of the above	463	87.4	87.4	100.0
	Total	530	100.0	100.0	



How much do you give an evaluation of the success of this medication from 10?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	more than 5	145	27.4	42.4	42.4
	less than 5	82	15.5	24.0	66.4
	10	115	21.7	33.6	100.0
	Total	342	64.5	100.0	
Missing	System	188	35.5		
	Total	530	100.0		



Discussion:-

This study was based on a number of **530** participants, from this study as the number of patients have used of immune-modulating drugs in skin disease is 62, The results indicated that most respondents say that they give the success of the medication more than 5 from 10, 27%. prevalence of who do not face any side effects 87.36%. The current study showed statistically significant (P value is 0.01) and (P value is 0.05),

Conclusion:-

Results showed that 27% of the samples gave the drugs a rating greater than 5 out of 10, and by 21% gave the drugs a rating 10 out of 10.

Recommendation:-

We recommend setting up health education programs about the geriatric diseases specially kidney disease and hypertension, this health problem must be presented broadly and beneficially and, in a way, that everyone understands, as most deal with the kidney disease by ignoring and not being important, work should be done on health conferences and medical discussions on that.

Acknowledgement:-

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Ethical considerations

Administrative approval will be sought from the unit of biomedical ethics research committee Ethical approval will be sought from the ethical committee of the faculty of medicine, king abdulaziz university. An informed consent will be sought from the participants.

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APPENDIXES:-

Questionnaire

Gender

- Female
- Male

Age

- below 18 years old
- 18-25 years old
- 26-33 years old
- 34- 40 years old
- above 40 years old

Nationality

- Saudi
- Non- Saudi

Have you ever used one of these medications?

- Methotrexate: Otrexupâ,Rasuvo,Rheumatrex,TrexallTM,Amethopterin, Methotrexate Sodium , MTX
- Azathioprine :Imuran.
- Cyclosporin: Gengraf, Neoral, and Sandimmune.
- I have not used any of these drugs

For how long?

- 7-10 days
- 15-30 days
- More than 30 days
- 3-6 months
- Nothing of the above

Select the indication to use?

- psoriasis
- Chronic plaque psoriasis
- Atopic eczema
- Hand dermatitis
- Chronic photosensitivity dermatitis
- Lichen planus

- Bullous pemphigoid
- Drug-induced nummular dermatitis
- Nothing of the above

Select the side effects?

- Low blood counts
- Mouth sores
- Poor appetite
- Skin rash, reddening of the skin
- Nausea and vomiting
- Alopecia
- Skin photosensitivity
- None of the above

How much do you give an evaluation of the success of this medication from 10?

- more than 5
- less than 5
- 10