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# A Clinical and Biochemical Evaluation of Effectiveness of Isotretinoin in Patients with Nodulocystic Acne

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***Abstract***

***Background and Objective****: Nodulocystic acne is a serious and most common among young people influencing their physical and emotional well being. The research was conducted to establish, how isotretinoin influenced health and symptoms of individuals diagnosed with nodulocystic acne who visited the Department of Dermatology, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry. The research took place during three years at Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry at Dermatology Department.*

***Material and Method****: The study included 125 patients with nodulocystic acne, were selected from the patients attending Dermatology Department OPD, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry. Women in reproductive age group or planning for pregnancy was tested for urine pregnancy test. All patients were evaluated for baseline CBC, blood glucose, liver function test, kidney function test and tests for fat in blood, ultrasound abdomen and pelvis was done for all the women to rule out PCOD. The patients began with 0.5mg/kg per day of isotretinoin which was given in a single dose. Patients were checked every month for a period of 15-20 weeks of treatment, patient was reviewed every month to check the improvements, how the disease responded and side effects. Every month end blood tests were done. Those patients who relapsed faster than three months following treatment were not given another course. At the end of every month blood tests complete blood count, liver function , kidney function and lipid profile were done.*

***Results****: The study showed most of that most of the study participants had a family history of nodulocystic acne, especially male patients (76%), as opposed to female patients. Most lesions were found on the patients faces (84%), followed by face and trunk (16%), and fewer patients had on the mid chest and upper arm (2.4%). The primary cause of nodulocystic acne was stress (64%), other reasons were extreme heat (8%), certain food habits (4%), and trying different cosmetic items & homemade solutions (24%). Majority of patients have lip related complaints (92%), muscle pain (4%), peeling of skin in the hands (1.6%), nose bleed (1.6%) . (36%) patients had nodulocystic acne for 10-12 months and (28%) had acne for 7-9 months .*

*Conclusion: isotretinoin helps to treat nodulocystic acne ,when started early, carefully monitored and also when stress and environment issues are also addressed.*

*Keywords: Nodulocystic acne, Isotretinoin, side effects, treatment outcome*

## INTRODUCTION

Nodulocystic acne is a severe form of inflammatory acne characterized by the presence of nodular breakouts and cysts. Nodular acne develops deep under your skin, causing painful, red bumps. It can result in significant damage to the skin with great impact on quality of life [1]. It can be primarily caused by clogged pores, excess oil production, and bacterial overgrowth within the skin. Hormonal fluctuations, genetics, and certain medications can also contribute to its development. Other factors include stress, certain skincare products and even diet can also play a role in triggering or worsening nodular acne. The treatment of choice for acne conglobata is using retinoids like isotretinoin for 20 to 28 weeks or, in some cases, even longer. Consider adding oral prednisone (1 mg/kg/d) for 14 to 28 days upon starting isotretinoin [2]. Acne is estimated to affect 9.4% of the global population, making it the eighth most prevalent disease worldwide [3]. Epidemiological studies have demonstrated that acne is most common in postpubescent teens, with boys most frequently affected, particularly with more severe forms of the

disease. It is one of the most widespread dermatologic conditions and is classified as acne vulgaris and adult acne. Acne vulgaris is a dermatosis of adolescents and adults up to 24 years of age and is found in up to 57.8% [4]. If adolescent acne is not treated until the age of 25 years, or if its onset is after this age, we refer to adult acne. Estimates of the annual prevalence of acne vulgaris in the population generally range between 3% and 4%, depending on the study [5,6]**.** The major impact is seen on the structure called the pilosebaceous unit. Substances from the endocrine system regulate the processes of sebocytes making lipids, reproducing and becoming different cells [7]. When androgens bind to the androgen receptors (ARs) found in large numbers in the sebaceous gland, these glands become more active. Therefore, the study was aimed to assess the effectiveness of using isotretinoin on the symptoms and biochemistry of nodulocystic acne.

## MATERIALS AND METHODS

125 patient cases were chosen from those who attended dermatology department Sri Lakshmi Narayana Institute of Medical Sciences Puducherry. After a full history and examination, only patients with nodulocystic acne and at least two nodules were permitted in the study.
**Aim:** To evaluate the effectiveness of isotretinoin in patients with nodulocystic acne

### Inclusion Criteria:

- Those patients who have continued different treatments for extended periods such as oral antibiotics, creams containing antibiotics, benzoyl peroxide and topical retinoids, without getting substantial improvement were included.
- People between the ages of regardless of gender, could take part in the study.

### Exclusion Criteria:

- Those with cholesterol above normal levels, apparent depression, a reaction to light or hypersensitivity to parabens were excluded.
- No women who might get pregnant while participating in the trial were included if they were not using contraception.

### METHODS:

- Women in reproductive age group or planning for pregnancy were tested urine pregnancy test before starting treatment with isotretinoin.
- Part of the baseline tests were CBC for blood count, blood glucose, tests for liver enzymes (AST, ALT, alkaline phosphatase, serum bilirubin), tests for kidney function (blood urea, serum creatinine) and tests for fats in blood (serum triglycerides, total cholesterol, LDL, HDL).

The physician performed an abdominal and pelvic ultrasound on female patients to check for any polycystic ovary syndrome (PCOS). 125 patients took part in the study. 95 patients were male. 30 female patients are included. Following meals, the patients all began with 0.5 mg/kg per day of isotretinoin which was given in a single dose. Patients were checked every month during the 15-20 weeks of treatment. For the first 3-4 months after starting treatment, appointments happened each month to check the improvements, how the disease responded and side effects. Treatment was stopped if patients had not improved by the 6–8-week mark. He had monthly blood tests for CBC, liver function (LFT), kidney function (RFT) and lipid profile. Those patients who relapsed faster than three months following treatment were not given another course based on the guidelines. Patients were not able to keep taking tetracyclines, vitamin A supplements, azoles or macrolides while they were part of the study. The medication should be taken right after a meal high in fat with water, patients should stay out of the sun, use sunscreen, not drive at night, limit contact lens use and take other precautions. They were told to visit the clinic every 15 days or let the study know if any side effects appeared during the research period.

## RESULTS

In this prospective study, majority of participants were male (n=95; 76%) followed by female (n=30; 24%). Half of the study participants (n = 66; 52.8%) were between the ages of 14 and 18; the next largest group was between the ages of 19 and 23 (n = 45; 36%). The age range of 24-28 years had fewer patients (8%) than the 29–33-year age group (n=4; 3.2%). The results showed that most of the study participants had a family history of nodulocystic acne, especially male patients (n=95; 76%) as opposed to female

patients. Males are more likely to inherit the disease than females, suggesting that genetics may be a significant factor. Most lesions were found on the patients' faces (n= 103; 84%), followed by face and trunk (n= 20; 16%). and fewer patients had them on the mid-chest and upper arms (n=3; 2.4%). The patients did not report any lesions on their scalp, shoulders, or back, which are typical of nodulocystic acne on the face. The primary cause of nodulocystic acne, as reported by (n=80; 64%) of patients, was stress. Other reasons included extreme heat (10; 8%), certain food habits (n=5; 4%) and trying different cosmetic items and homemade solutions (n=30; 24%). It is evident that a number of environmental, mental, and lifestyle variables can exacerbate acne. Majority of patients (n= 115; 92) had four lip-related complaints (cracking, cheilitis and dry and sore mouth) followed by muscle pain (n=5; 4%) peeling of the hands (n=2; 1.6%), nosebleeds (n=2; 1.6%) headaches and dry skin. The study subjects had nodulocystic acne for 10–12 months (n=45; 36%) and 7-9 months (n=35; 28%), respectively.

In this prospective study, majority of participants were male (n=95; 76%) followed by female (n=30; 24%). The details are presented in Table 1.

**Table 1. Gender wise distribution Among the Participants (n=125)**

| Description | Number(n=125) | Percentage (%) |
|---|---|---|
| Male | 95 | 76 |
| Female | 30 | 24 |

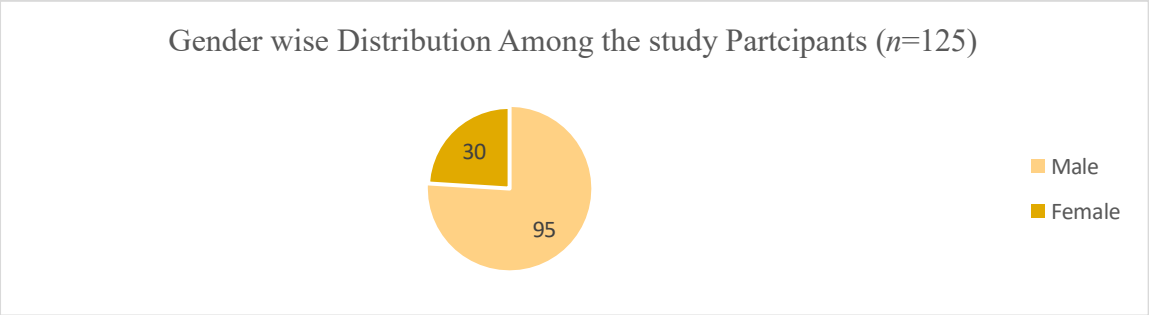


**Figure 1. Gender wise Distribution among the study participants**

Among the participants, most of them were aged between 14-18years (n=66; 52.8%), followed by 19-23 years (n=45; 36%). The data are presented in Table 2.

**Table 2. Age wise distribution of adverse drug reaction (n=125)**

| Age (In years) | Number (n=125) | Percentage (%) |
|---|---|---|
| 14-18 | 66 | 52.8 |
| 19-23 | 45 | 36 |
| 24-28 | 10 | 8 |
| 29-33 | 4 | 3.2 |

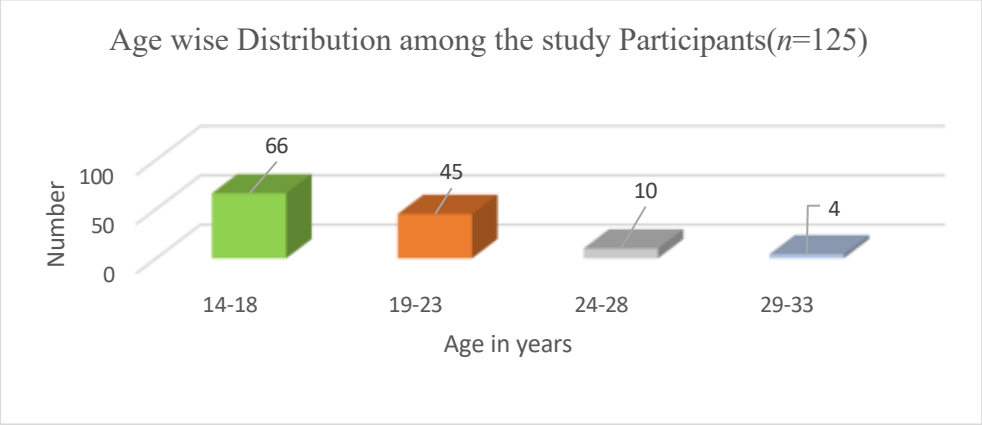


**Figure 2. Distribution of age among the study participants**

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Among the study participants, the majority of the study participants were having family history of nodulocystic acne (n=95; 76%). The data are presented in Table 3.

**Table 3. Distribution of Family history among the Participants (n=125)**

| Description | Number (n=125) | Percentage (%) |
|---|---|---|
| Yes | 95 | 76 |
| No | 30 | 24 |

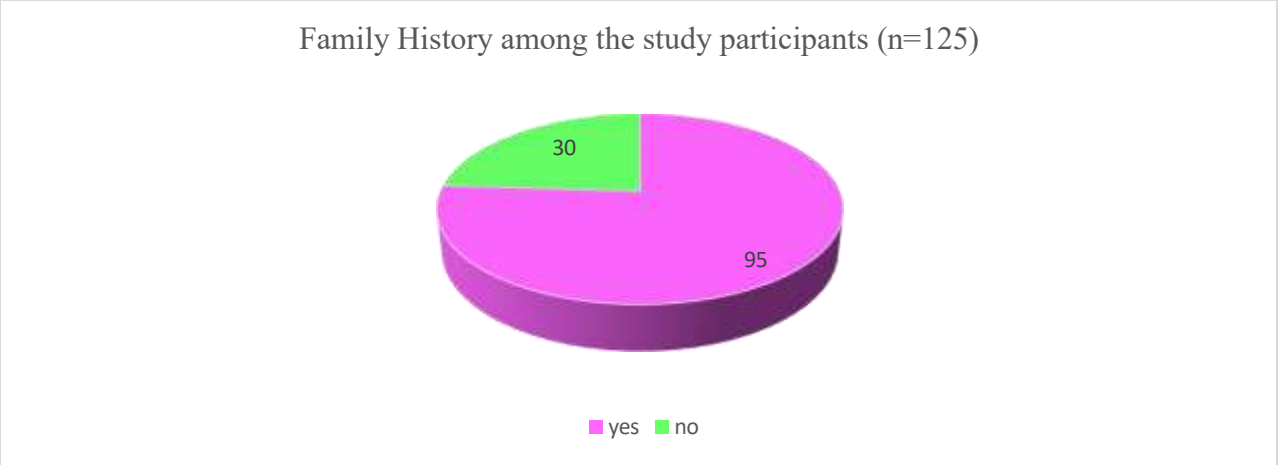


**Figure 3. Distribution of Family history among the study Participants**

Among the study participants, majority of them had the site lesions were on face (n= 103; 84%), followed by face and trunk (n= 20; 16%). The data are presented in Table 4.

**Table 4. Distribution of site lesions among the Participants (n=125)**

| Site of Lesions | Number (n=125) | Percentage (%) |
|---|---|---|
| Face | 103 | 84 |
| Mid Chest | 03 | 2.4 |
| Upper Arms | 03 | 2.4 |
| Face and Trunk | 20 | 16 |

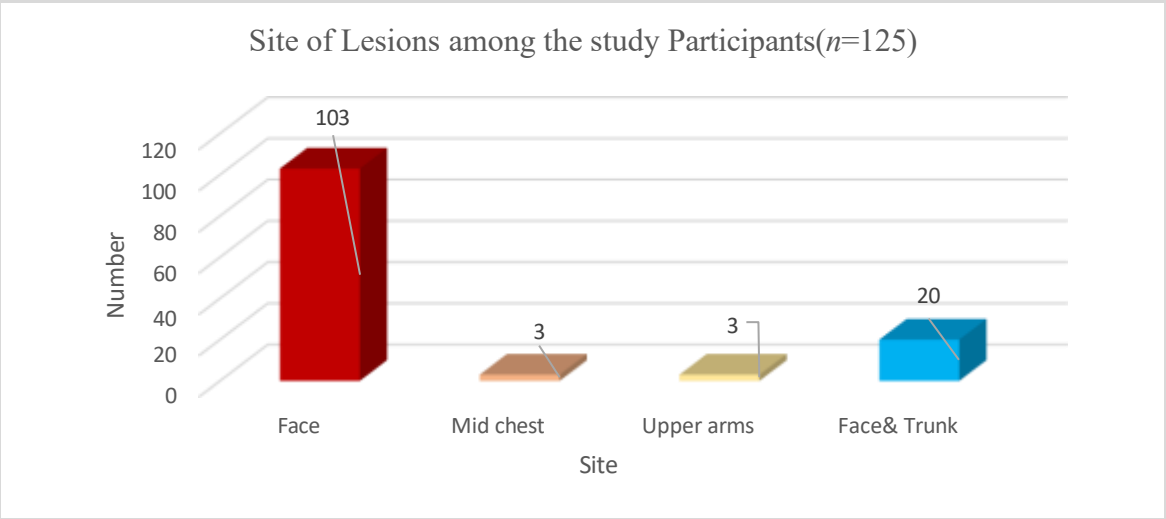


**Figure 4. Distribution of site of Lesions among the study Participants**

Among the study participants, majority of the participants had an experience in undergoing stressful life events (n=80; 64%), followed by use of cosmetics and home remedies (n=30; 24%). The data are presented in Table 5.

**Table 5: Factors Associated in patients with Nodulocystic Acne (n=125)**

| Factors | Number (n=125) | Percentage (%) |
|---|---|---|
| Stress | 80 | 64 |
| Hot Weather | 10 | 8 |
| Diet | 05 | 4 |
| Use of Cosmetics and Home Remedies | 30 | 24 |

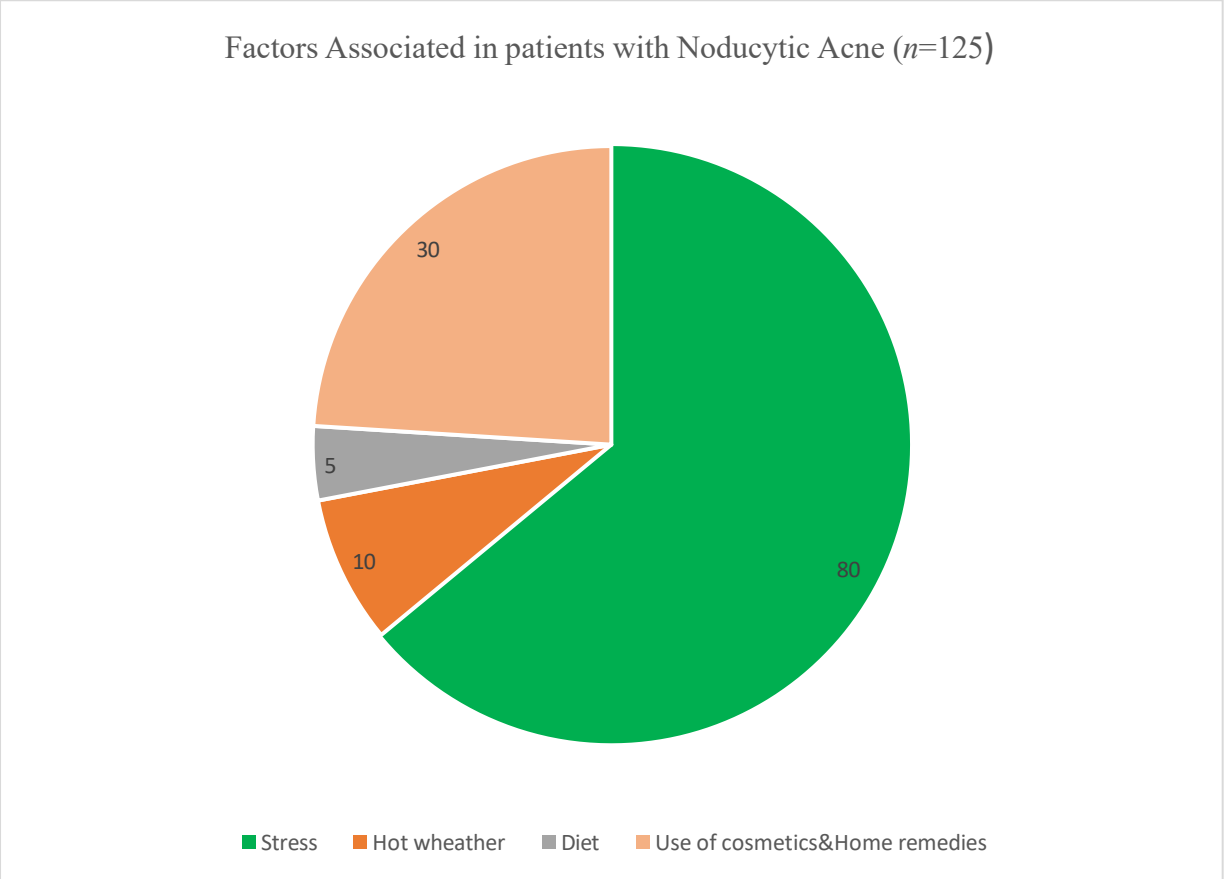


**Figure 5. Factors Associated in patients with Nodulocystic Acne**

Among the study participants, the most of them had the adverse effects of cracking of lips, cheilitis dry and sore mouth (n=115; 92%), followed by muscle pain (n=5; 4%). The details are presented in Table 6.

**Table 6: Type of reactions observed from reported ADRs on Patients Receiving Isotretinoin Treatment**

| Type of Reactions | No. of Patients (n=125) | Percentage (%) |
|---|---|---|
| Cracking of lips, cheilitis, dry and sore mouth | 115 | 92 |
| Muscle pain (myalgias) | 05 | 4 |
| Peeling of palms | 02 | .1.6 |
| Nosebleeds (epistaxis) | 02 | 1.6 |
| Headaches | 02 | 1.6 |
| Dryness of facial skin (xeroderma) | 04 | 3.2 |

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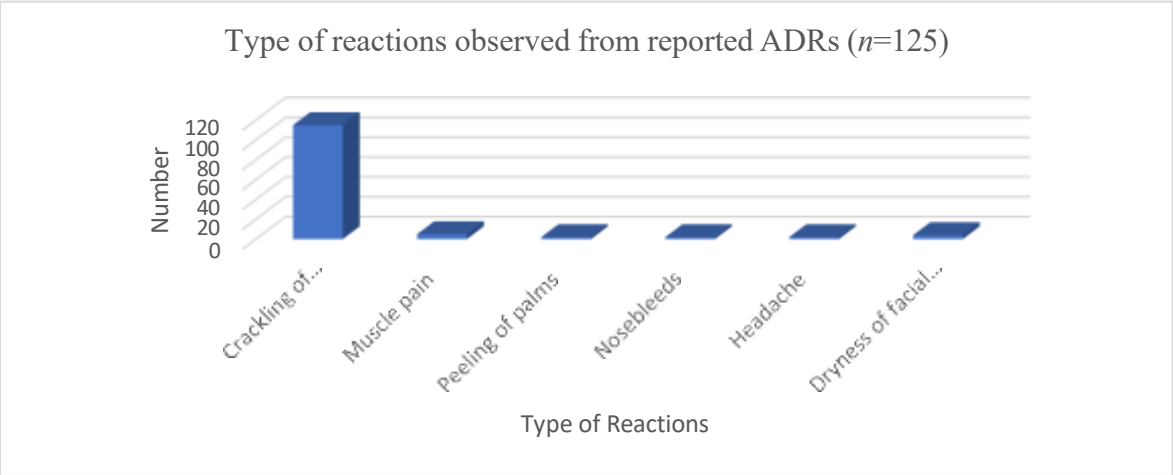


Figure 6. Type of reactions observed from reported ADRs on Patients receiving Isotretinoin Treatment

Among the study participants, majority of the participants were having the duration of nodulocystic acne 10-12months (n=45; 36%), followed by 7-9months (n=35; 28%). The details are presented in Table 7.

**Table 7: Duration of Acne among the study participants (n=125)**

| Duration (Months) | Number (n=125) | Percentage (%) |
|---|---|---|
| 0-3 | 20 | 16% |
| 4-6 | 25 | 20% |
| 7-9 | 35 | 28% |
| 10-12 | 45 | 36% |

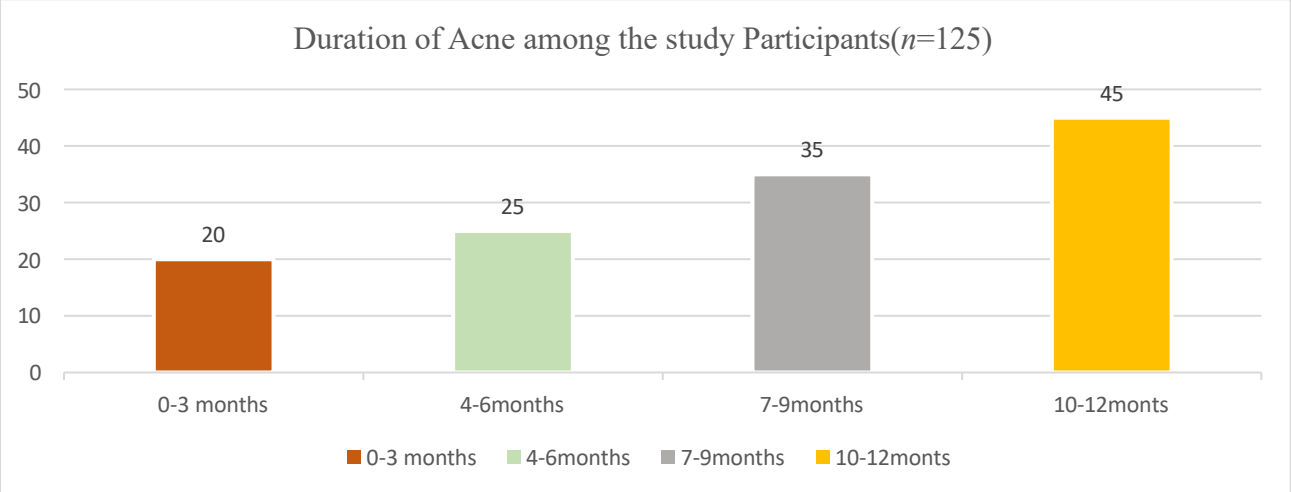


**Figure 7. Duration of Acne among the study Participants**

## DISCUSSION

The prospective study was aimed to evaluate the effectiveness of isotretinoin in patients with nodulocystic acne. The prevalence and incidence of nodulocystic acne are more common in male population in this study. The findings shows, the majority of the population are male (n=44; 73%) and participants in this study were above the age group of 14-18 years, which was comparable to previous study by Dhir et al.,2008 [8] in which young adult population predominated (n=26; 43.3%). In the study population, the face was the most commonly affected site, which was similar to this finding by Mahajan et al,. 2003[9]. This could be owing to the fact that male populations are more likely to get severe acne since their androgen levels are usually higher than those of females. This is what many studies show, including the idea that people with nodulocystic acne are mainly in their teen and early 20s, a time when hormones play an important

role. As sebum is produced in greater amounts because of androgen-driven sebaceous gland activation, this fits with the idea that androgens help cause acne.

In this study, the majority (84%) of patients had lesions on their faces, a typical feature of nodulocystic acne. Some patients instead had a small number of lesions on their mid-chest, upper arms or face and trunk. Intriguingly, none of the patients had lesions on their backs, shoulders or scalp, a thing that is not common for nodulocystic acne. Perhaps, the sample consisted mainly of people with facial involvement or the lesions were more likely to stay local in this group. About one-third (36%) of patients said that stress was the top reason why they developed nodulocystic acne. Other elements were the heat, specific foods and using cosmetics and homemade remedies. This suggests that many things such as stress and pollution, can make acne worse. The most common side effects experienced during isotretinoin treatment were cracking of the lips, dry mouth and cheilitis which were in line with what past studies found (88% of those treated experienced these). Besides these symptoms, some patients had muscle pain, peeling palms, nosebleeds, headaches and xeroderma. These side effects usually caused no serious problems and most patients continued their medication. Many of the patients (84%) had acne for at least six months. Because nodulocystic acne is chronic, people usually need to take isotretinoin for a long period to get better results. Overall, the study shows that timely and targeted care is very important for nodulocystic acne, especially in the young and points out that genetic, hormonal and environmental conditions greatly influence its occurrence.

## CONCLUSION

This study underlines how nodulocystic acne, being a critical form of acne vulgaris, highly influences both physical health and psychological well-being of people, mainly adolescents and young adults. Most cases of nodulocystic acne are seen in males, mainly during their late teenage and early twenties, linking the condition to hormone changes, mainly from androgens. Researchers found that having relatives with acne increased a patient's risk, especially for males which indicates there may be a strong genetic factor involved. Using isotretinoin for acne greatly reduced the seborrhea, acne nodules and the appearance of acne. Even so, many users experienced problems such as chapped lips, a dry mouth and cheilitis which had been mentioned in previous studies. Most of the side effects were not serious, though this still shows that patients and doctors must stay aware during treatment. Nodulocystic acne is generally chronic and most patients had been dealing with it for at least six months, so their doctors often needed to provide ongoing treatment. More than one-third of patients listed stress as a significant cause and factors such as high temperatures, poor diet and cosmetics were also mentioned as causes. This shows us that acne can develop for many reasons and managing it needs a focus on physical and mental health. All in all, isotretinoin helps treat nodulocystic acne well when started early, carefully monitored and stress and environment issues are also addressed. Many biological, hormonal and environmental elements help bring about the condition, showing that a balanced treatment plan is important.

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