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RESEARCH ARTICLE

FORDYCE GRANULES AS A POTENTIAL CHAIRSIDE CLINICAL PREDICTOR FOR HYPERCHOLESTEROLEMIA: A CROSS-SECTIONAL STUDY

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Abstract

Background: Fordyce's granules (FGs) are ectopic sebaceous glands commonly located in the oral cavity, appearing most frequently on the buccal mucosa, vermilion border of the lips, and occasionally in the retromolar areas. Owing to its lipid content, there has been conjecture regarding a potential connection between FGs and dyslipidemia, a disorder characterized by elevated lipid levels that may be linked to ectopic lipid deposits in different tissues.

Aim: The purpose of this cross-sectional study was to ascertain whether Fordyce's granules could be used as a chair side clinical marker to identify those who are at risk for dyslipidemia.

Methods: The cross-sectional study was carried out at Saveetha Dental College and Hospitals in Chennai over the course of a year, from June 2023 to May 2024. 100 adult dental patients between the ages of 18 and 60 were examined clinically by an oral medicine specialist to determine whether Fordyce granules were present. Every participant had their blood drawn in order to determine their lipid levels. Analysis was performed on the data to determine predictors for hypercholesterolemia.

Results: Patients with detectable oral FG had a mean age of 50.2 ± 12.3 years. A mean total cholesterol of 250.3 ± 41.7 mg/dL ($p < 0.001$) and mean HDL cholesterol value of 42.0 ± 8.1 mg/dL ($p < 0.05$) were seen to be associated with presence of FG with statistical significance. The odds ratio (1.083) indicates that for every unit increase in TC, the odds of FG increase by 8.3%.

Conclusion: The presence of oral Fordyce granules may indicate increased total cholesterol predisposing individuals to hypercholesterolemia. Factors such as age, smoking, and diabetes mellitus showed no association between Fordyce granules and lipid profiles.Previously regarded as a normal anatomical variation, fordyce granules should be considered in conjunction with other risk factors to identify possible dyslipidemia.

Keywords: Cholesterol, serum, lipids, mouth, dyslipidemias

Introduction

Fordyce's granules (FGs) are ectopic sebaceous glands commonly located in the oral cavity, appearing most frequently on the buccal mucosa, vermilion border of the lips, and occasionally in the retromolar areas. They are also found on the genital mucosa, including the glans penis and labia minora. These granules, initially documented by Kölliker and later described by Fordyce, are now understood as normal anatomical variations rather than pathological findings[1,2]. Clinically, FGs are small, asymptomatic, yellowish to whitish papules that range from 0.2 to 2 mm in diameter and often remain stable throughout life. Although present in up to 80-90% of individuals, FGs become more visible after puberty and are more common in those with oily skin[3-5].

The pathogenesis of FGs remains unclear, although their lipid-rich composition is similar to typical sebaceous glands, comprising triglycerides, wax esters, and squalene, which create a lipid barrier on skin surfaces[6,7]. This lipid content has led to speculation about a possible link between FGs and dyslipidemia, a condition marked by abnormal lipid levels, which could be associated with ectopic lipid deposits in various tissues[8]. While FGs are generally harmless, recent studies have explored their potential connection with systemic lipid imbalances. For instance, findings suggest that higher FG density may correlate with hyperlipidemia, indicating that these granules could have diagnostic relevance. Either the increased fatty content of clinically undetectable glands, which makes them readily evident during the oral examination, or the de novo differentiation of cells, which results in more oral FGs, are two ways that hyperlipidemia may contribute to the development of oral FGs[9].

Despite several studies documenting the prevalence of FGs, few have examined their clinical significance. Given the role of dyslipidemia as a risk factor for cardiovascular disease, identifying visible markers such as FGs could aid in early detection and intervention. This cross-sectional study seeks to determine whether the presence of Fordyce's granules may serve as an accessible clinical marker for identifying individuals at risk for dyslipidemia.

Methods

This study was a cross-sectional study conducted between a time period of one year from June 2023 - May 2024 at Saveetha Dental College and Hospitals, Chennai. Adult dental patients aged 18-60 years who visited the OP during the given time frame, were subjected to a thorough clinical examination by an Oral Medicine specialist, to identify the presence of Fordyce granules. Patients with no previous history of lipid-altering medications or medical conditions affecting lipid metabolism who were willing to participate in the study were included. Patients with genetic lipid disorders, those on treatment for dyslipidemia at the time of examination, patients with any other oral mucosal lesion and pregnant patients were excluded from this study. Approval was obtained from the Institutional Human Ethical Committee (Reference number – IHEC/SDC/UG-1962/23/OMED/192) and informed consent was obtained from all the included patients prior to study commencement.

Figure1. Oral fordyces granules on buccal mucosa
Figure 2. Oral fordyces granules labial mucosa

Sample size calculation

Sample size was calculated considering the prevalence of FG of 5.3% and a prevalence rate of dyslipidemia of 37.5 % among adult Indian population along with a standard alpha level of 0.05[10,11]. For this study, with 90% power, a sample size of approximately 29 participants was needed to detect an association between the presence of Fordyce's granules and dyslipidemia based on the given prevalence rates. However, to ensure robust results and given the time frame of 1 year of the study, we included a larger sample size of 100 patients to account for potential variability.

Bloodsamples was collected from all participants to measure lipid levels. Blood samples were analyzed using standardized laboratory techniques. The patients were not mandatorily under overnight fasting of 12 hours at the time of collecting blood samples. This was not practical, as the included patients were those visiting a dental hospital for routine dental treatments. However, lipid profiles can often be assessed without fasting, especially for total cholesterol (TC) and HDL cholesterol, as non-fasting values tend to be comparable to fasting ones. Hence, in this case we assessed only the TC and HDL values. Patients with high TC or low HDL levels were classified as having dyslipidemia based on the following thresholds[12,13].

1. Total Cholesterol (TC):
    - Desirable: TC < 200 mg/dL
    - Borderline High: TC 200–239 mg/dL

- High: TC ≥ 240 mg/dL

2. HDL Cholesterol:
   - Low HDL (risk factor):
     - Men: HDL < 40 mg/dL
     - Women: HDL < 50 mg/dL
   - Normal HDL: HDL ≥ 40 mg/dL for men and ≥ 50 mg/dL for women
   - Protective (high HDL): HDL ≥ 60 mg/dL

Dyslipidemia is classified as present if either total cholesterol is 200 mg/dL or higher or HDL is below the thresholds specified (40 mg/dL for men, 50 mg/dL for women)[12,13].

Statistical Analysis

The collected data were entered into Microsoft Excel 2016 and analyzed using IBM SPSS Statistics for Windows, Version 29.0 (Armonk, NY: IBM Corp). Descriptive statistics, including frequency and percentage analyses, were applied to summarize categorical variables, while the mean and standard deviation (SD) were calculated for continuous variables. An independent sample t-test was conducted to assess significant differences between bivariate samples in independent groups, and the Chi-square test was used to evaluate associations in categorical data. Binary logistic regression with the enter method was applied to identify predictors of Fordyce's Granules presence. A p-value of less than 0.05 was considered statistically significant for all analyses.

RESULTS

100 patients were included in the study which constituted 51 males and 49 females. Out of 35 patients who had FG, 35.3% (18) were males and 34.7%(17)were females(p> 0.05) **(Table 1)**.

Table 1Association between gender and presence of FG

			Fordyces Granules		Total
			Present	Absent	
DM	Yes	Count	19	24	43
		%	44.2%	55.8%	100%
	No	Count	16	41	57
		%	28.1%	71.9%	100%
Total		Count	35	65	100
		%	35%	65%	100%

Pearson Chi-Square Test, p = 0.950

The proportion of non-smokers (78%) was higher in the study population compared to that of smokers (22%).

Among the 35 patients with Fordyce's granules, only 4 reported a history of smoking, while the other 31 were non-smokers. The relationship between smoking history and presence of FG was found to be statistically insignificant in this study **(Table 2)**.

Table 2 Association between smoking history and presence of FG

			Fordyces Granules		Total
			Present	Absent	
Smoking History	Non-Smoker	Count	31	47	78
		%	39.7%	60.3%	100%
	Smoker	Count	4	18	22
		%	18.2%	81.8%	100%
Total		Count	35	65	100
		%	35%	65%	100%

Pearson Chi-Square Test, p = 0.061

19 (44.2%) patients had presence of FG and were diabetic, as well. 16 (28.1%) of the study population were not diabetic, although, had presence of FG (p>0.05) **(Table 3)**.

Table 3 Association between Diabetes Mellitus and presence of FG

			Fordyces Granules		Total
			Present	Absent	
DM	Yes	Count	19	24	43
		%	44.2%	55.8%	100%
	No	Count	16	41	57
		%	28.1%	71.9%	100%
Total		Count	35	65	100
		%	35%	65%	100%

Pearson Chi-Square Test, p = 0.094

Among the 35 patients with presence of FG, 25(71.4%) patients were found to be dyslipidemic. 40.3% of dyslipidemic patients had clinical presence of FG in their oral cavity ($p > 0.05$) **(Table 4)**.

Table 4. Association between Dyslipidemia status and presence of FG

			Fordyces Granules		Total
			Present	Absent	
Dyslipidemia	Yes	Count	25	37	62
		%	40.3%	59.7%	100%
	No	Count	10	28	38
		%	26.3%	73.7%	100%
Total		Count	35	65	100
		%	35%	65%	100%

Pearson Chi-Square Test, p = 0.154

Patients classified to be dyslipidemic had a mean age of 50.2 ± 12.3 years. A mean total cholesterol of 250.3 ± 41.7 mg/dL ($p < 0.001$) and mean HDL cholesterol value of 42.0 ± 8.1 mg/dL ($p < 0.05$) were seen to be associated with presence of FG with statistical significance **(Table 5)**.

Table 5. Interaction of Mean values of age, TC and HDL with FG

	Fordyces Granules	N	Mean	SD	P value
Age	Present	35	50.2	12.3	0.592
	Absent	65	48.9	11.4	
TC	Present	35	250.3	41.7	0.0000
	Absent	65	213.0	23.3	
HDL	Present	35	42.0	8.1	0.017
	Absent	65	45.9	7.3	

Independent Samples T Test

Results of logistic regression analysis exploring the association of Fordyce's granules with specific predictors included in the model is represented **(Table 6)**.

Table 6. Logistics Regression

		B	S.E.	Wald	df	P value	Exp(B)	95% C.I. for EXP(B)	
								Lower	Upper
Step 1a	Age	-0.047	0.036	1.678	1	0.195	0.954	0.889	1.024
	Gender(1)	-0.005	0.690	0.000	1	0.994	0.995	0.258	3.844
	Smoking(1)	1.376	0.915	2.262	1	0.133	3.959	0.659	23.785
	TC	0.079	0.021	13.645	1	0.0002	1.083	1.038	1.129
	HDL	-0.017	0.066	0.070	1	0.791	0.983	0.863	1.119
	Dyslipidemia(1)	2.105	1.024	4.229	1	0.040	8.205	1.104	60.995
	DM(1)	0.513	0.897	0.327	1	0.568	1.670	0.288	9.690
	Constant	-17.687	6.425	7.557	1	0.006	0.000		

A. Variable(s) entered on step 1: Age, Gender, Smoking History, Total Cholesterol, HDL, Dyslipidemia Status, DM.

B: The regression coefficient, S.E.: Standard error of the regression coefficient, df: Degrees of freedom, Exp(B): Odds ratio

Age is not a significant predictor of FG. The odds ratio (0.954) suggests a slight negative association, but it is not statistically meaningful. Gender does not significantly impact the odds of FG. The odds ratio (0.995) indicates no meaningful change in odds based on gender. The odds ratio (3.959) suggests smokers may have higher odds, but this finding lacks statistical support. Total cholesterol is a statistically significant predictor of FG ($P < 0.05$). The odds ratio (1.083) indicates that for every unit increase in TC, the odds of FG increase by 8.3%. HDL is not a significant predictor of FG. The odds ratio (0.983) suggests a negligible negative association. Dyslipidemia is a significant predictor of the outcome ($P < 0.05$). The odds ratio (8.205) indicates that individuals classified as dyslipidemic have significantly higher odds (8.2 times) of FG. Diabetes mellitus is not a significant predictor of FG. The odds ratio (1.670) suggests a potential positive association, but it is not statistically meaningful.

DISCUSSION

Oral Fordyce granules (FGs) are frequently identified during routine dental check-ups and are regarded as normal anatomical variations[13]. However, rarely they have been suggested to be associated by hypercholesterolemia[14]. One case report of dermoid cyst in the oral cavity highlights that presence of FG in the site was the only clinical finding[15]. A study done among Middle East population reported a very high prevalence (89.7%) of detectable FGs in oral cavity[16]. Another study from Karachi reported the presence of oral FG in half (50.9%) of the included sample[17]. A study from Iraq noted that only 25% of the study population had FG in

the oral cavity[18]. A large cohort study on European population revealed a very low prevalence rate of 1.2% for oral FG[19]. This suggests a varying wide range of prevalence of FG in oral cavity reported in the literature. The current study on dental patients visiting a dental hospital observed the clinical finding of oral FG in 35 out of 100 patients documenting a prevalence rate of 35% for the same.

FG, Age and Gender

J H Olivier assessed the prevalence of FG on the prolabial and oral mucous membranes among South African population which was found to be 62.07% in adult males and 57.25% in adult females[20]. In a study by Shahzad et al., compared to female patients (37%), male patients had a higher prevalence of Fordyce's granules (57%). They found a higher frequency in patients older than 20 years. Fordyce's granules were shown to be highly prevalent in the third and fourth decades of males and the fourth and fifth decades of females[17]. In two individual studies Cawson et al., and Pindborg JJ et al., have concluded that prominence of FG increases with increase in age. Whereas, Flinck A et al, found that the number of these granules decreased with advancing age. No statistical dominance for any particular age group was reported by Gaballah KY et al[16]. In the current study it was recorded that the FG presence was associated significantly with a mean age of 50.2 years favoring the former study results.

FG and smoking status

The current study only 11.4% of individuals with FG had positive smoking history. It should be noted that the study sample constituted a majority of nonsmokers and the association obtained was statistically insignificant. In the study by Gaballah et al., The detection of FGs did not show a statistically significant difference between smokers (98.8%) and non-smokers (87.7%)[16]. On the other hand, UM Olivio et al., reported that compared to present smokers (0.9%, n = 3) or past smokers (0.7%, n = 4), non-smokers (1.5%, n = 15) had higher levels of Fordyce granules[19]. Another epidemiological study on Iranian population also revealed Forduces granules presence to be more in non-smokers (42%) than smokers (26.7%)[21]. These studies along with present study results supports the smoking can obscure the appearance of Fordyce granules. This could be an impact of thickening of the oral epithelium and increased melanin[22].

Diabetes Mellitus and FG

Fordyce granules did not show any significant relation with the diabetes mellitus in the study by Jahanbani et al[21]. A study on oral alterations in diabetics suggested that 2.3% of patients with type II DM had FG[23]. Souza MGM et al., reported that FG is common in type II DM[24]. However, the current study did not find any statistically significant association between DM and FG.

FG and Dyslipidemia

AR Diajil concluded that fordyce granules were found in one-fourth of patients with hypercholesterolemia, however the majority of cases had normal triglyceride levels, HDL, LDL, and VLDL levels. The lipid profile and these granules did not correlate, according to the chi-square test. Their study however included patients who visited a primary health centre and were subjected to serum lipid profiling after 8-12 hours overnight fasting. Also, they scored the test values as normal, borderline and high which was different from the classification criteria used for dyslipidemia in this study. Correlation analysis were performed on the data, while the present study assessed the odd's ratio values using regression analysis[18].

Gaballah KY et al also evaluated the possible interplay between FG and hypercholesterolemia. They scored the FG based on the number of spots. It was seen that among the individuals scored with 6-30 spots the number of patients with hypercholesterolemia was twice (n=76) than in those with controlled lipid levels (n=33). They pointed out that the individuals with an elevated lipid profile had higher chance of exhibiting a surge in the number of FG in the oral cavity[16].

Another study tried to explore the association between blood grouping, FGs and serum lipid profile. Their study results suggested that those with AB positive blood group had higher number of FGs and also, the individuals having the same blood group were more likely to have hypercholesterolimia[25].

The current study results are consistent with the previous, though scanty, literature which indicates a possible association between FGs and lipid profile. Dyslipidemia was found to be associated more with those in their 6th decade of life. With statistical significance, the presence of FG was linked to a mean HDL cholesterol value of 42.0 ± 8.1 mg/dL and a mean total cholesterol of 250.3 ± 41.7 mg/dL. A logistic regression analysis was applied which revealed that total cholesterol (P = 0.0002) and dyslipidemia (P = 0.040) were the significant predictors in this model in comparison with other variable such as age, gender, smoking, HDL, and diabetes that did not show a statistically significant impact. This suggested that total cholesterol and dyslipidemia play a substantial role in clinically detectable oral FGs, while other factors may require further investigation in larger or different samples.

Limitations, Advantages and Future Prospects

Not taking the triglyceride and LDL levels for the lipid profile can be taken as one of the limitations of this study. This made comparison of dyslipidemia status of patients with existing studies challenging due to the variation in the classifying criteria. Serum cholesterol can be influenced by other confounding factors such as dietary habits, family history, physical activity and alcohol consumption which were not taken into account in this analysis. In subsequent research, histochemical analysis can be done for the fordyces granules in patients with and without deranged lipid profile to further elucidate the interplay between serum cholesterol and oral FGs.

Nevertheless, the current study is unique in other aspects. Considering the studies in literature, firstly most of the related studies report epidemiological data which have studied FG as a mucosal variant or alteration in different population[20,21]. The studies which have tried to assess the possibility of FG as having an association with the systemic status is extremely limited in number.

The current study done on South Indian population stands out in its attempt to evaluate the role of FG in the lipid status of dental patients visiting a hospital for dental treatment. For applicability, in dental clinical set up, we assessed TC and HDL levels for the lipid profile without mandatory fasting. Non-fasting tests are generally sufficient for cardiovascular risk prediction, making testing more convenient for patients. However, fasting samples may still be required if initial levels are high, as non-fasting triglycerides can be significantly elevated due to recent food intake. We considered testing only TC and HDL levels as these readings do not tend to be significantly affected by in case of non-fasting. The American Heart Association and other major guidelines now accept non-fasting lipid panels in routine testing, reserving fasting measurements for more detailed assessments if initial triglyceride levels are unusually high[12,13]. Another noteworthy feature of this study is that the oral examination of included patients for the presence of FG was performed by an Oral Medicine specialist. Many general practitioners tend to not identify the granules as FGs or may ignore the finding[26].

Hence, in this study screening by a specialist ensured that cases were not missed out. Many research studies are ongoing to assess the lipid profile in dental patients for various clinical applications in dentistry[27-30].

This study which underscores a possible association of oral FGs with dyslipidemia in dental patients could indicate the potential use of oral FGs as a surrogate marker for hypercholesterolimia.

CONCLUSION

Within the confines of this cross-sectional study, the authors conclude that presence of oral fordyces granules can point towards an increase in total cholesterol and a drop in the high-density lipoprotein, thereby, resulting in a predisposition to hypercholesterolemia. Other factors like age, smoking habit and a history of diabetes mellitus were not seen to have any link with oral fordyces granules in comparison with the lipid profile.

Dentists often encounter patients with prominent fordyces granules during routine examination. The results of this study can be an add-on to the deficient literature base which emphasizes the need to consider these granules to be interconnected with the patient's lipid profile. Previously touted as a normal anatomical variation, dentists should bear in mind this possible interdependence. If a patient exhibits prominent fordyces granules along with other risk factors for dyslipidemia or cardiovascular disorders like age, obesity, smoking history, family history, stress, poor diet and lack of physical activity, then the dentist should consider evaluating the lipid profile to rule out dyslipidemia.

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Conflicting interest

None

Ethical Approval

Institutional Human Ethical Committee/Saveetha DentalCollege/Undergraduate-1962/23/Oral Medicine/192) and was conducted in accordance with theDeclaration of the World Medical Association.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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