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RESEARCH ARTICLE

Assessment of risk factors in development of gall stone disease in type 2 diabetic population in India: A cross sectional study of 100 patients.

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Abstract

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..... Background: Gall stone disease is associated with approximate 50% patients of long standing type 2 diabetes mellitus. There are a lot of risk factors for developing gall stone disease in metabolic syndrome like diabetes mellitus. Aim: Our current study aimed to identify the risk factors of age, body mass index (BMI), family history of gall stone disease, physical activity and duration of diabetes in developing gall stone disease in Indian type 2 diabetic population. Method and materials: we conducted this study on 100 randomized cross sectioned diabetic patients with 20 healthy control subjects attending Shri Guru Ram Dass medical college and hospital. All required investigation and examination was done. The association between age, BMI, duration of diabetes, family history of gall stonesand activity level of patients with gallstone was evaluated. Result: In our study we found significant association of developing gall stone in diabetic patients according to BMI, family history of GSD, physical activity and duration of diabetes. There is no significant difference found with reference to increasing age though duration of diabetes carries significant difference. Conclusion: In our study increasing age did not correlated significantly for GSD but duration, BMI, physical activity and family history of GSD proved to be risk factor in diabetic for gall stone disease.

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Introduction:-

Diabetes is an "iceberg" disease. Currently the number of cases of diabetes worldwide is estimated to be around 150 million. This number is predicted to double by 2025 (a prevalence rate of about 5.4 per cent). Diabetes is more prevalent in Europe and America than Asian countries. It is estimated that 20 per cent of the current global diabetic population resides in South-East Asia Region. The number of diabetic persons in the countries of the Asian region is likely to triple by the year 2025 increasing from the present estimates of about 30 million to 80 million. ^[1]. Roughly80% of people with diabetes in developing countries, of which India and China share the larger contribution. It is estimated that the total number of people with diabetes in 2010 to be around 50.8 million in India, rising to 87.0 million by 2030^[2].

Diabetes mellitus is one of the risk factors in cholesterol gallstones. Individuals with diabetes mellitus are reported to have a 2-fold to 3-fold increase in the incidence of cholesterol gallstones ^[3]. There are several important mechanisms in formation of lithogenic bile. The most important is increased biliary secretion of cholesterol. This may be associated with obesity, metabolic disorder like diabetes, high caloric and cholesterol rich diets or drugs (clofibrate)^[4]. Other important mechanism in cholesterol gall stone formation is gall bladder hypo motility leading to delayed gall bladder emptying and stasis ^[5]. Gallbladder distention and stagnation associated with diabetic neuropathy allows such supersaturated bile to precipitate its cholesterol content and the resultant stones to grow ^[6].

A number of factors in diabetic patients including old age, female gender, family history of gall stones, parity, diet, obesity and BMI have been associated with increased risk of GSD^[7].

Aim of our current study is to check the prevalence of gall stone disease in diabetic population and to evaluate the association of various risk factors in diabetic patients with the development of gall stone disease.

Method and material:-

The study was conducted on 100 clinically diagnosed diabetic patients attendingShri Guru Ram Dass medical college, Amritsar. 20 normal age and sex matched individual constituted the control group to evaluate the prevalence of GSD.

Eligibility criteria includes: 1.TYPE 2 –Diabetic patient of age group 40-70 were comprised the study group. 2. Written consent for the trial was obtained from all the patients after examining them in detail and consent of institutional ethical committee was obtained.

Exclusion criteria: The following exclusion criteria were adherent to the study.

- All non-diabetic patients
- The patient of age group less than 40 years or more than 70 years
- Patients who refused to give informed written consents
- History of alcohol consumption

After recording the consent of the subjects in the study group as well as the control group detailed history was recorded regarding the symptoms of diabetes, family history of gall stone disease.Body mass index (BMI) was calculated according to Quetelet's formula^[8] and subjects were accordingly categorized.

Туре	BMI (Kg/m2)
Underweight	<18.5
Healthy weight	18.5-24.9
Overweight	25-29.9
Obese class I	30-34.9
Obese Class II	35-39.9
Obese Class III	>40

After completing all investigation and examination Ultrasound examination of abdomen was performed after 12 hours of overnight fasting in the morning using real time scanner with 3.5 megahertz transducer. Both cases and control group were assessed. Presence of gall stone and sludge were considered positive for gall stone disease.^[9] Statistical analysis of the data was done using two by two table , chi square value and p value. Degree of freedom was kept to be 1 and p value <.05 was regarded as significant for all table data's.

Results:-

1. Prevalence:-

Out of 100 diabetic patients 45 develop gall stone disease and 55 did not develop while in control healthy group only 3 subjects had evidence of GSD while 17 had no evidence. So prevalence of GSD in diabetic in our study was 45%.

Table1. Showing prevalence of GSD in study and control subjects

GSD	Study Grou	Study Group			Control Group	
05D	No.		%age		No.	%age
Absent	55	55			17	85
Present	45	45			3	15
GSD GSD	Chi- square value	re value p value S		Signi	Significance	
	6.250	.012 Sig		Significant		

2. Age distribution:-

As shown in table 2 the mean age in the GSD positive patients was 57.09 ± 8.52 years and the mean age in GSD negative patients was 55.27 ± 8.09 years respectively. The difference of age was statistically non-significant.

TABLE-2 DISTRIBUTION OF PATIENTS ACCORDING TO AGE IN STUDY GROUP BETWEEN GSD POSITIVE AND GSD NEGATIVE

Age	GSD +		GSD -	
(years)	No.	%age	No.	%age
40-50	11	24%	16	29%
50-60	12	27%	21	38%
60-70	22	49%	18	33%
Total	45	100%	55	100%
Range	42-68		40-69	
Mean±SD	57.09±8.52		55.27±8.09	
t	-1.090			
р	.278			
S	Non-Significant			

3. BMI :

The table 3 shows majority of patients with GSD have BMI >25 kg/m², these majority are overweight constituting >80% of GSD patients. On statistically analysis correlation of BMI with incidence of gall stone, it shows that there is a very significant positive correlation of BMI with the incidence of gall stone in diabetic population. (P value 0.005)

TABLE 3 SHOWING DISTRIBUTIONS OF PATIENTS ACCORDING TO BMI IN STUDY GROUP BETWEEN GSD POSITIVE AND GSD NEGATIVE PATIENT

BMI	GSD +	GSD +		GSD -	
(kg/m^2)	No.	%age	No.	%age	
18.5-24.9	9	20	20	36.4	
25-29.9	13	28.9	18	32.7	
≥30	23	51.1	17	30.9	
	Chi- square value	p value	Significance		
GSD	4.928	.005	Significant		

4. Family history of gall stone disease:-

In the study group GSD was present in 16 (35.6%) of patients with positive family history of GSD and 29 (64.4%) of patients with negative family history of GSD. GSD was absent in 40 (72.7%) of patients with positive family history of GSD and in and 15 (27.3%) of patients with negative family history of GSD which was statistically highly significant.

Table 4 showing distribution according to family history of GSD in study group

Family History	GSD +	GSD +		GSD -	
Failing History	No.	%age	No.	%age	
Present	16	35.6	40	72.7	
Absent	29	64.4	15	27.3	
	Chi- square value	p value	Significance	Significance	
GSD	14.823	.000	Highly Signi	ficant	

5. Distribution according to physical activity level:-

Table 5 shows that out of 45 GSD patients 35 were of sedentary life style while in patients without GSD majority was moderate and heavy workers. On statistical analysis this correlation was found to be significant with p value .0001.

Table 5. DISTRIBUTION OF PATIENTS ACCORDING TO PHYSICAL ACTIVITY IN STUDY GROUPBETWEEN GSD POSITIVE AND NEGATIVE SUBJECTS

Dhusical Activity	GSD +	GSD +		GSD -	
Filysical Activity	No.	%age	No.	%age	
Heavy	3	6.7	17	30.9	
Moderate	7	15.5	21	38.2	
Sedentary	35	77.8	17	30.9	
	Chi- square value	p value	Significance		
GSD	22.253	.0001	Highly Significant		

6. Duration of diabetes:-

The table 6 shows that majority of diabetic 52% with GSD had duration >10 years. Mean age for GSD is 11.33 ± 4.41 and in non GSD group is 9.16 ± 3.82 .on statistical analysis this was significant with p value .010.

TABLE-6DISTRIBUTION OF PATIENTS ACCORDING TO DURATION OF DIABETES IN STUDY GROUP BETWEEN GSD POSITIVE AND GSD NEGATIVE

Duration	GSD+		GSD-	
(years)	No.	%age	No.	%age
6 months - 5	3	7%	6	13.3
5-10	14	31%	23	51.1
10-15	19	42%	16	35.6
>15	9	20%	-	-
Range	3-19 years		2-16 years	
Mean+SD	11.33±4.41		9.16±3.82	
t	-2.634			
р	.010			
S	Significant			

Finally there is significant difference between presence and absence of Gall stone according to BMI, family history of GSD, physical activity and duration of diabetes. There is no significant difference found between presence and absence of Gall stone with reference to age though duration of diabetes carries significant difference.

Discussion:-

1. prevalence:-

In the study group the prevalence of GSD was present in 45% patients with diabetes mellitus and in control the prevalence of GSD was present in 15% patients, it was statistically significant. It was in accordance the study done by Al-Bayatiet all ^[10] (2012) in which the incidence of gallstones is 33% in diabetic patient and 17% in non-diabetic patients, it is also statistically significant. Study done by Elmehdawi et al ^[11] (2009), Gupta et al^[12] (2008) also shows significant increase in incidence of GSD in diabetic patients.

2. Age:-

In our study group distribution of GSD according to increasing age was not significant. These were similar to findings of Chhabra et $al^{[13]}$ and Drshivamkhare et $all^{[14]}$. While in the other study done by Elmehdawi et $al^{[11]}$ (2009) and Pagliarulo M1^[15] et all the distribution according to age is statistically significant.

3. BMI:-

In the study group BMI in GSD positive patients was >25 kg/m2 in 80% and <25kg/m2 in 20% patients. This was statistically significant. These results were in accordance with study done by Mendez-Sandez et $al^{[16]}$ (2005) where

BMI >25kg/m2 is present in 80% of study groups with GSD. This is statistically significant. The study done by Elmehdawi et al^[11] (2009) and Sun et al^[17] (2009), Al-Kayatt and Al-Youzbaki^[18] (2008) also show that significant relationship was present between BMI and GSD in diabetic patients.

4. Family history of gall stone disease:-

In the study group family history of GSD was present in 35.6% GSD positive patients. This was statistically significant. These result was similar to the study done by Elmehdawi et al^[11] (2009) and Al-Kayatt and Al-Youzbaki^[18] (2008) who also showed positive correlation between family history of GSD and the incidence of GSD in diabetes patients.

5. Physical activity:-

Our study showed statistical significant result of association between sedentary life style and incidence of GSD. This was similar to study done by Al-Kayatt and Al-Youzbaki^[18] (2008) showing that there is significant correlation between sedentary life style and incidence of GSD. The study done by Kumari and Krishna^[19] (2010) also shows positive correlation between sedentary life style and incidence of GSD.

6. Duration of diabetes:-

In the present study the mean duration of diabetes in study group in patient with GSD was 9.163 ± 82 and in patients without GSD was 8.673 ± 28 years.

These results were similar to the study done by Elmehdawi et al^[11] (2009) in which the mean duration of diabetic patients with GSD is 12.57 ± 7 years and in patients without GSD the duration is 10.6 ± 6.8 years, this is statistically significant. The study done by Agunloye et al^[20] (2013) shows significant correlation between duration of diabetes and GSD.

Conclusion:-

Various modifiable and non modifiable risk factors are correlated with the association of type 2 diabetes mellitus and gall stones. Among the non modifiable risk factors family history of gall stone disease and duration of diabetes was positively correlated in our study while increasing age was not a risk factor. Among modifiable risk factors which were found to be significant on our study were BMI and sedentary life style. Importance of our study lies in respect to early identification and control of the modifiable risk factor.

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