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Gall bladder stones disease– prediction constructs calculator.

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ABSTRACT… Objective: To calculate the constructs and determine the predictors of gall bladder stone disease. **Study Design:** Randomized Control study. **Setting:** Mohtarma Shaheed Benazir Bhutto Hospital and Sandeman Provincial Teaching Hospital Quetta. **Period:** 2019 to 2020. **Material & Methods:** A total of 392 patients were enrolled by non-probability consecutive technique from outpatient department and those referred from medicine department. The inclusion criteria were patients of any age group and gender. The exclusion criteria were the patients who were physically handicap interfering with anthropometric indices and patients suffering from hemolytic disease. The patients were divided into two groups, the disease group (patients having gall bladder stone) were 207 patients and control group (patients without gall bladder stone) were 185 patients. In all patients' anthropometric indices and lipid profile was performed. The data was collected on prescribed proforma. The constructs were analyzed by using SPSS version 23. **Results:** The overall mean age of the patients was 43.97$\pm$11.75 years. There were 355 (90.6%) female and 37 (9.4%) male. The height and weight were found significant in female patients ($p - 0.012$ & < 0.001 respectively). The waist circumference was significant in male ($p - 0.017$), while hip circumference and waist to hip ratio in female (p -0.015 & <0.001 respectively). The body mass index was above normal in female 122 (62.1%), while in male patients 7 (62.3%) in disease category. In female patients with high risk cholesterol group had 1.5 times more risk than desirable group and low level of HDL had 4 times more risk than normal level. In male patients with elevated LDL was statistically significant. **Conclusion:** Gall bladder stone disease predictors determinants are female in their late forties or early fifties, raised body mass index, hip circumference and waist to hip ratio and elevated cholesterol level, while male in their late forties or early fifties, raised waist circumference and elevated LDL & Triglycerides.

Key words: Anthropometric Indices, Gall Stone Disease, Lipid Profile.

INTRODUCTION

The modern aim of public health focuses on primary prevention rather than treatment. In developed countries, more than 85% of gallstones are cholesterol stones. About 20 million people in the USA (15% of the population) have gallstones.[1] In Pakistan the prevalence of gall bladder stone is 10.2%.[2] The construct of gall bladder stone varies widely. The people often speak of the four F(s) (Female, forty plus, fatty and fertile), which are said to be the four basic factors for gall bladder stones synthesis. The pathological conditions like chronic hemolytic syndrome, cirrhosis of liver, diabetes mellitus and hypothyroidism are the established etiological factors.[3,4] High intakes of refined sugar and low vegetable protein favor gallstone formation. Consumption of excessive saturated fats coupled with less physical activity and high waist hip ratio were the most significant predictors and point toward unhealthy lifestyle practices.[5] Some immunosuppressive drugs like cyclosporine and tacrolimus are thought to be prolithogenic.

Various pathophysiological constructs of gall bladder stone formation like super saturation of bile constituent with cholesterol, defect in biliary lipid metabolism, biliary dismotility and prolong bile intestinal transit hypertriglyceridemia impairs gall bladder motility due to decrease sensitivity of cholecystokinin enhances the risk of gall bladder stone formation.[6] Sedentary life style, lack of

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exercise and altered dietary factors especially fat consumption leads to deranged anthropometric indices. The genetic factors like apoliprotein E2 provides natural protection, while E4 increases gall bladder stone formation.[7] A remarkable shift in the trend of gall-stone disease from middle aged, fertile, fat females to young asthenic females in their twenties was also observed.[8] The purpose of this study was to identify the common constructs, which enables the community to identify their own risk for gall bladder stone disease and adopts preventive measures because "prevention is better than cure".

MATERIAL & METHODS

This randomized control study was conducted in Mohtarma Shaheed Benazir Bhutto Hospital Quetta and Sandeman Provincial Teaching Hospital Quetta during Jun 2019 to Oct 2020 on 392 patients (n=392). The objective was to calculate the constructs and determine the predictors of gall bladder stone disease. The patients were enrolled through outpatient department and those referred from medicine department. The sampling technique was non probability consecutive. The inclusion criteria were all those patients of any age and gender who gave the informed consent. The exclusion criteria were all those patients who were physically handicap interfering with anthropometric indices and suffering from hemolytic disease.

The patients were divided into two groups. The disease group (patients having gall bladder stone; on ultrasonographic examination having intraluminal, echogenic, mobile foci that were gravity-dependent and created a clear acoustic shadow) were 207 patients and control group (patients having normal gall bladder) were 185 patients. Brief history about patient's demography was taken. Patient's marital status, number of children and use of contraceptives history was also recorded. Anthropometric indices were measured. Weight was measured in the upright position to the nearest 0.1 kg using a calibrated beam scale. Height was measured without shoes to the nearest 0.1cm using a calibrated standiometer. Body mass index was calculated by weight in Kg divided by height in meter square. Waist circumference to the nearest of 0.1 cm was measured between the midpoint of lower rib cage and iliac crest. Hip circumference was measured to the nearest of 0.1 cm at the greatest horizontal circumference below the iliac crest at the level of greater trochanter. Waist to hip ratio was calculated. Fasting total lipid profile was also performed. All these data was collected on prescribed performa.

The operational definitions described as normal parameters were as follow. The waist circumference (WC) in male < or = 102 cm was normal, while above it considered raised. The WC in female < or = 88 cm was normal, while above it considered as raised. The waist to hip ratio (WHR) in male 0.95 or below as low risk, 0.96 to 1.0 as moderate risk and > 1.0 as high risk. The WHR in female 0.80 or below as low risk, 0.81 to 0.85 as moderate risk and > 0.85 as high risk. The body mass index (BMI) regardless of gender was recorded as less than 18.5 kg/m^2 underweight, 18.5 to 24.9 kg/m^2 normal, 25.0 to 29.9 kg/m^2 overweight, 30.00 to 34.9 kg/m^2 mild obese, 35.0 to 39.9 kg/m^2 moderate obese and 40.0 kg/m^2 or above considered as extremely obese.

The fasting cholesterol < 200 mg/dl desirable, 200- 240 mg/ dl border line and >240 mg/ dl considered as high risk. The high density lipoprotein (HDL) normal range in male was 27 – 67 mg/dl, while in female it was 34 – 88 mg/ dl. The triglyceride (TG) < or = 165 mg/dl was considered normal, while above it considered abnormal. The low density lipoprotein (LDL) < 130 mg/dl desirable, 130 – 159 mg/ dl border line and = or > 160 mg/dl considered as high risk.

The recorded data was analyzed on SPSS version 23.0. The study variables were age, gender, marital status, parity, use of contraceptives, anthropometric indices and lipid profile. The mean age and standard deviation was recorded. Female to male ratio was recorded. The mean weight, height, waist circumference, hip circumference, waist to hip ratio and mid arm circumference recorded. The mean of fasting cholesterol, triglyceride, low density lipoprotein and very low density lipoprotein was also recorded. The

significance of all variable was checked by Chi square test and level of significance determined. The P < 0.05 was considered to be significant. All the results of the studies were compared with local and international studies.

RESULTS

This study was conducted in Mohtarma Shaheed Benazir Bhutto Hospital Quetta and Sandeman Provincial Teaching Hospital Quetta on 392 patients (n = 392). The overall mean age of the patients was 43.97±11.75 years. The age ranges from 21– 76 years. There were 355 (90.6%) female and 37 (9.4%) male. The female to male ratio was 9.59: 1. The patient having gall bladder stone (Disease group) majority of the patients 102 (49.3%) were below the age of 40 years, (96.6%) were married and having average 5 children. The concept of using contraceptive pills was found among 25 (12.1%) women. The ratio of nonworking women to working women was found to be 5.3:1. (Table-I).

The average height of male patients were 161±12.60 cm, while of female patients 153±9.18 cm. The height of female patients was found significant (p=0.012). The average weight of male patients was 72.16±9.05 kg, while of female patients 64.51±11.08 kg. The weight of female patients was found significant (p=<0.001).

The average waist circumference of male patients was 98.16±8.27 cm, while of female patients 94.83±12.19 cm. The waist circumference was well above the normal range and it was found significant (p=0.017). The majority of female patients 147 (74.4%) and male patients 9 (75%) in disease group had raised waist circumference. The average hip circumference of male patients was 101±5.80 cm, while of female patients 97.76±11.47 cm. The hip circumference of female patients was found significant (p= 0.015).

S. No.	Characteristics	Disease Group	Control Group
1.	**Age:** < 40 Years 41 to 50 Years > 50 Years	 102 (49.3%) 65 (31.4%) 40 (19.3%)	 64 (34.6%) 57 (30.8%) 64 (34.6%)
2.	**Gender:** Female Male	 195(94.2%) 12(5.8%)	 160 (88.5%) 25 (13.5%)
3.	**Marital Status:** Married Unmarried	 200 (96.6%) 7(3.4%	 176 (95.1%) 9 (4.9%)
4.	**Number of Children:** No Child < 3 Children 4 to 6 Children 7 to 9 Children 10 or > 10 Children	 8 (3.9%) 50 (14.1%) 102(45.4%) 30(14.5%) 17(8.2%)	 9 (4.9%) 25 (13.5%) 145 (68.4%) 6 (3.2%) Nil
5.	**Use of Contraceptive Pills:** Yes No Married Unmarried Male Patients	 25(12.1%) 167(80.7% 3(1.4%) 12(5.8%)	 5 (2.7%) 151 (81.6%) 25 (13.5% 4 (2.2%)
6.	Occupation Nonworking women working women	 166 (80.2%) 41 (19.8%)	 145 (78.4%) 40 (21.6%)

Table-I. Demographic profile of study participants.

The average waist to hip ratio of male patients was 0.96±0.04 cm, while of female patients 1.96±9.81 cm. The average value in male patients was in moderate risk while in female it was in high risk category. The waist to hip ratio of female patients was found significant (p= <0.001). The majority of female patients 187 (95.9%) were in high risk group while 7(58.3%) male patients were in moderate risk group in disease category. The patients in high risk category of waist to hip ratio had significance over low to moderate group. The body mass index was above normal in female patients 122 (62.1%), while in male patients 7 (62.3%) in disease category. The female patients who were overweight to extreme obsess had two times more risk of gall bladder stone than underweight to normal female and it was found significant (<0.001). (Table-II & III)

In female patients with borderline to high risk cholesterol group had one and half time more risk of developing gall bladder stone than desirable group and it was found significant. In female patients with below normal high density lipoprotein had approximately 4 times more risk of developing gall bladder stone than patients with normal high density lipoprotein but it was not found to be significant. In male patient with border line to high risk category of low density lipoprotein had statistically significant than desirable category. (Table-IV)

DISCUSSION

The Gall bladder stone was first described by Antonio Benivenius in 1507, however the history of gall bladder stone backs to the era of Egyptian Mummies. Epidemiologic investigations conducted all over the world allowed for defining many new constructs that predispose development of the disease. It seemed appropriate to answer the question whether 4 x F canon (forty--the age over 40 years of age; female--gender; fertile--fertility; fat--obesity) still remains the basic canon among risk factors that determine the development of cholelithiasis. The data revealed that 4 x F canon as the risk factor has not lost any significance.[9,10]

Obesity proved to be one of the strong risk factors associated with Gall bladder Stone Diseases (GSD).[11] The increasing prevalence of obesity and its association with GSD expected to increase the prevalence of cholelithiasis.[12]

Anthropometric Variables	Disease Group	Control Group	P-Value
Height (Cm)			
Male	161±12.60	166±11.62	0.134
Female	153±9.18	151±8.73	0.012
Weight (Kg)			
Male	72.16±9.05	66.96±15.28	0.201
Female	64.51±11.08	71.43±17.22	<0.001
Waist circumference (Cm)			
Male	98.16±8.27	90.44±14.84	0.510
Female	94.83±12.19	100.79±16.43	0.017
Hip circumference (Cm)			
Male	101.75±5.80	92.80±16.84	0.510
Female	97.76±11.47	106.76±14.48	0.015
Waist to Hip Ratio			
Male	0.96±0.04	0.99±0.18	0.428
Female	1.96±9.81	0.95±0.07	<0.001
Mid Arm circumference (Cm)			
Male	30.75±1.91	27.76±3.3	0.327
Female	29.58±3.47	31.58±5.9	<0.001

Table-II. Anthropometric indices of study participants (Average values).

Anthropometric Measures	Disease Group	Control Group	Odd Ratio	95% CI	P-Value
Waist Circumference					
Female Normal	48 (24.6%)	73 (45.6%)	0.38	0.248- 0.811	<0.001
Female Raised	147 74.4%)	87 (54.4%)			
Male Normal	9 (75%)	18 (72%)	1.11	0.375- 3.294	0.847
Male Raised	3 (25%)	7 (28%)			
Waist to Hip Ratio					
Female Low to Moderate Risk	8 (4.1%)	15(9.4%)			
Female High Risk	187(95.9%	145(90.6%)	0.41	0.171- 1.002	0.045
Male Low to Moderate Risk	10 (83.3%)	21(84%)			
Male High Risk	2 (16.7%)	4 (16%)	0.97	0.28- 3.34	0.959
Body mass Index (Female)					
Under Weight to Normal Weight	74(37.9%)	34 (21.3%)	2.26	1.407- 3.650	0.001
Over Weight to Extreme Obese	121(62.1%)	126 (78.7%)			
Body mass Index (Male)					
Under Weight to Normal Weight	6(50%)	12(48%)	1.066	0.416- 2.67	0.909
Over Weight to Extreme Obese	6(50%)	13 (52%)			

Table-III. Anthropometric measures correlation of participants.

Lipid Profile Variables	Disease Group	Control Group	Odd Ratio	95% CI	P-Value
Cholesterol (Female)					
Desirable	143 (73.3%0	102 (63.7%			
Border Line to High Risk	52 (26.7%)	58 (36.3%)	1.564	0.995- 2.458	0.052
Cholesterol (Male)					
Desirable	9 (75%)	23 (92%)			
Border Line	3 (25%)	2 (8%)	0.261	0.037- 1.830	0.157
High Risk					
High Density Lipid (HDL) (Female)					
Normal	194 (99.5%)	157 (98.1%)	3.72	0.382-35.98	0.228
Below Normal	1 (0.5%)	3 (1.9%)			
High Density Lipid (HDL) (Male)					
Normal	12 (100%)	24 (96%)	0.66	0.529- 0.840	0.482
Below Normal	Nil	1 (4%)			
Low Density Lipid (LDL) (Female)					
Desirable	122 (62.6%)	111(69.4%)	0.738	0.473-1.150	0.179
Border Line	73 (37.4%)	49 (30.6%)			
High Risk					
Low Density Lipid (LDL) (Male)					
Desirable	4 (33.33%)	25 (100%)	0.138	0.056- 0.343	<0.001
Border Line	8 (66.66%)	Nil			
High Risk					
Triglyceride (TG) (Female)					
Normal	139(71.3%)	114 (71.3%)	1.002	0.631- 1.590	0.995
Above Normal	56(28.7%)	46 (28.7%)			
Triglyceride (TG) (Male)					
Normal	5 (41.7%)	25 (100%)			
Above Normal	7 (58.3%)	Nil	0.167	0.075-0.371	<0.001

Table-IV. Lipid profile and their correlation of study participants.

We observed that overall obesity was associated with GSD in both gender but it was statistically significant in female gender, while in male gender increased association proved but not statically significant. In present study other individual variables also showed statistically significant in female. Increased Waist Circumference (WC) (Female P Value -0.000- while Male P- Value 0.847), Waist to Hip Ratio (Female P- value 0.045- Male P-Value 0.959) and Body mass index (Female P-Value 0.001- Male P- Value 0.909). This may be due to estrogen influence on increased cholesterol secretion. Similar observation was reported by Hsi-Che Shen et al; in their study conducted in Taiwan.[13] Obesity and GSD association were also reported by Liu T et al (1) and Alishi YA et al; in their studies.[14] Obesity not only risk factor for GSD in adults but it also reported as independent risk factor in adolescents and young age group.[15] In present study 49.3% of patients was < 40 years, while in a study conducted by Shafique et al: almost half (48.13%) of their patients were younger than 30 years.[16] The present study revealed that GSD high prevalence in non-working women as compare to working women (80.2%Versus19.8%), while in study by Alishi YA et al;[14] the ratio was 44.2% vs 55.8% respectively. Similarly, Dhamnetiya D et al; observed that sedentary life style has strong association with development of GSD.[17] In present study house wives registered themselves as non- working. In our society work burden of house wives are equal to or even more than those who are working as Bhutta mazdoor (brick making workers) and Hari (Agriculture worker) as evident in a study conducted by Ahmed W et al; the house wives were in majority as compare to employees (53.84% versus 26.93%).[18]

Literature agreed that increased level of cholesterol, LDL and triglycerides are strongly associated with GSD but many studies failed to show statically significance, while low level of HDL associated with GSD reported highly significant.[18,19] In our study we observed that low level of HDL was associated in GSD but not significant, however increased level of cholesterol was significant in female and HDL were not statically significant in both genders, while LDL and triglycerides association was statically significant only in male gender disease group. In female disease group the Odd ratio for cholesterol was 1.564, 95% CI: 0.995-2.458 and p-Value 0.052, while in male patient Odd ratio 0.261, 95% CI: 0.037-1.830 and p-value 0.157. HDL in female gender showed Odd ratio 3.72, 95% CI: 0.382-35.98, and P-Value 0.228, while in male gender Odd ratio 0.66, CI: 0.529-0.840 and 0.482 respectively. LDL in female disease group showed OR-0.738, 95% CI: 0.473-1.150, P-Value 0.179, while in male gender Odd ratio 0.138, CI: 0.056-0.343, P value 0.000. Triglycerides result in female was OR-1.002, 95% CI: 0.631-1.590, P-value 0.995, while in male gender Odd ratio 0.167, CI: 0.075- 0.371, P value 0.000. Jaleel F et al[19] and Hayat S et al;[20] also reported strong association of low-level HDL in contrast to present study, while other biomarker consistent with present study. Kumar J et al; also found significant risk association of high level of triglycerides and HDL with GSD.[21]

The study revealed a quick guide to community to assess their risk by measuring anthropometric indices and performing lipid profile. The individuals at risk can prevent the Gall bladder stone disease by changing their life style and modifying dietary pattern. The present study has certain limitations like low sample size. In future further studies needed to potentiate the findings. Moreover, the study results cannot be generalized due to other constructs of Gall bladder stone disease, which were not part of the study.

CONCLUSION

Gall bladder stone disease predictors determined are female in their late forties or early fifties, raised body mass index, hip circumference and waist to hip ratio and elevated cholesterol level, while male in their late forties or early fifties, raised waist circumference and elevated LDL & Triglycerides.

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2	Manzoor Ahmed	Data compilation, Analysis & intretation, Manuscript writing.	
3	Zulfiqar Khosa	Data collection, Laboratory tests, Literature search, Critical analysis.	
4	Rubina Naz	Data collection, Literature search, Critical analysis.	
5	Muhammad Zubair	Data collection, Literature search, Critical analysis.