

RESULTS

162 patients were enrolled in the study and divided between both groups, 82 patients in group 1 (LSG) and 80 patients in group 2 (OAGB). The distribution of different preoperative parameters is shown in figure (1).

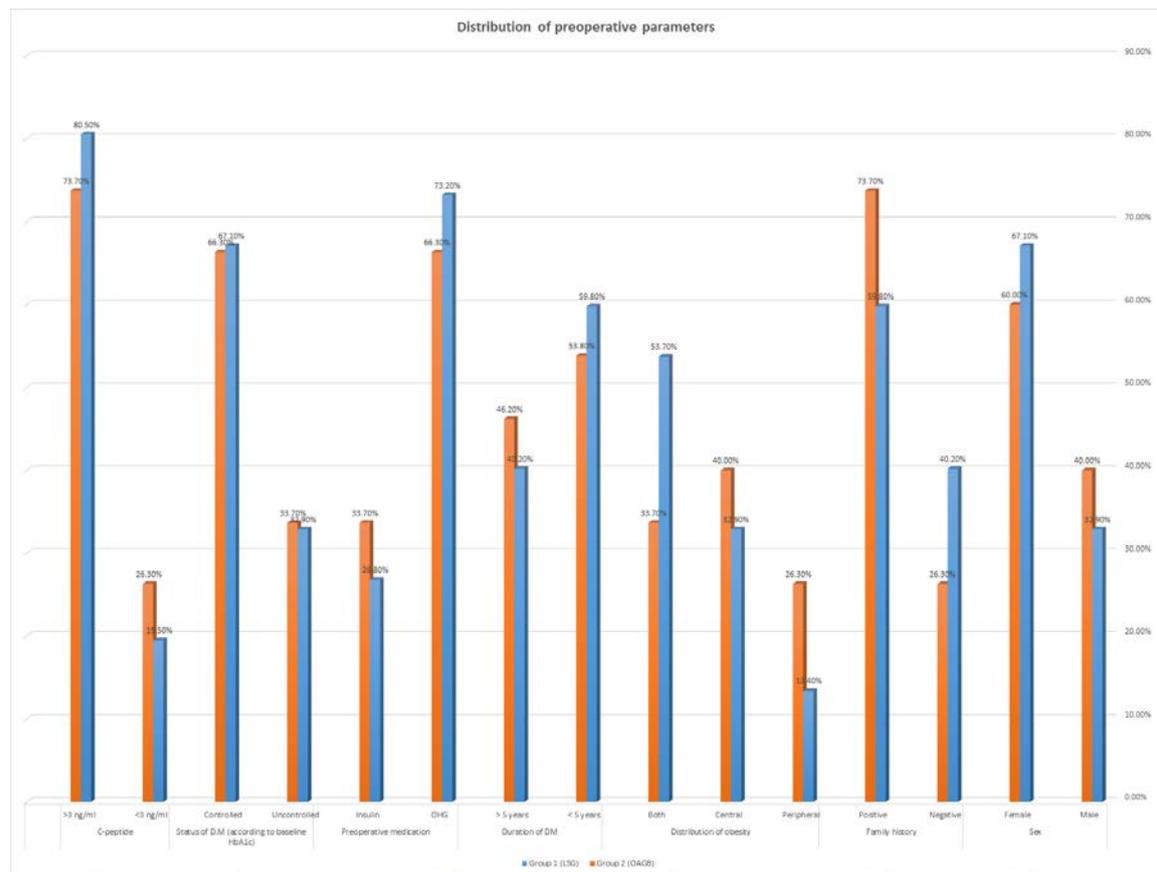


Figure (1): distribution of different preoperative parameters in both groups.

On comparing both groups as regards preoperative personal, biochemical, and medical characteristics, no statistically significant difference was found between both groups regarding these parameters. Table (1) shows the base line parameters of both groups and their statistical analysis.

| Variable | | Group | | | | P value | Sig. |
|---|---------------------|------------|-------|------------|-------|---------|------|
| | | LSG | | OAGB | | | |
| | | Mean | ±SD | Mean | ±SD | | |
| Age | | 37.73 | 9.35 | 37.47 | 9.05 | 0.911* | NS |
| Baseline BMI | | 51.93 | 9.78 | 52.33 | 9.41 | 0.421* | NS |
| Baseline C-peptide | | 3.77 | 1.25 | 4.13 | 1.37 | 0.549* | NS |
| Baseline FBS | | 145.27 | 12.78 | 149.67 | 12.27 | 0.514* | NS |
| Baseline HbA1c | | 8.21 | 0.88 | 8.10 | 0.92 | 0.326* | NS |
| Variable | | Group | | | | P value | Sig. |
| | | LSG | | OAGB | | | |
| | | N (%) | | N (%) | | | |
| Sex | Male | 27 (32.9%) | | 32 (40.0%) | | 0.592** | NS |
| | Female | 55 (67.1%) | | 48 (60.0%) | | | |
| Family history | Negative | 33 (40.2%) | | 21 (26.3%) | | 0.273** | NS |
| | Positive | 49 (59.8%) | | 59 (73.7%) | | | |
| Distribution of obesity | Peripheral | 11 (13.4%) | | 21 (26.3%) | | 0.235** | NS |
| | Central | 27 (32.9%) | | 32 (40.0%) | | | |
| | Both | 44 (53.7%) | | 27 (33.7%) | | | |
| Duration of D.M (yrs.) | < 5 years | 49 (59.8%) | | 43 (53.8%) | | 0.593** | NS |
| | > 5 years | 33 (40.2%) | | 37 (46.2%) | | | |
| Preoperative medication | OHG | 60 (73.2%) | | 53 (66.3%) | | 0.573** | NS |
| | Insulin | 22 (26.8%) | | 27 (33.7%) | | | |
| Status of D.M (according to baseline HbA1c) | Uncontrolled > 8.5% | 27 (32.9%) | | 27 (33.7%) | | 1.0** | NS |
| | Controlled < 8.5% | 55 (67.1%) | | 53 (66.3%) | | | |
| C-peptide | <3 ng/ml | 16 (19.5%) | | 21 (26.3%) | | 0.542** | NS |
| | >3 ng/ml | 66 (80.5%) | | 59 (73.7%) | | | |

*Student t test. **Chi-square test. –NS: none significant.

Tables (1): Comparison between both groups as regards preoperative personal, biochemical, and medical data.

All operations in both groups were performed laparoscopically except for one case in group 2 which was converted due to increased airway pressure with insufflation. The mean operative time of group one was 63 minutes (range: 40-120 minutes). The mean operative time of group 2 was 98 minutes ranging between (range: 65-160 minutes).

This difference was found to be statistically significant. No cases of perioperative mortality were reported in the study. The perioperative complication rate (3 cases (3.8%) in group 1, 4 cases (5%) in group 2) was generally similar between both groups as shown in figure (2).

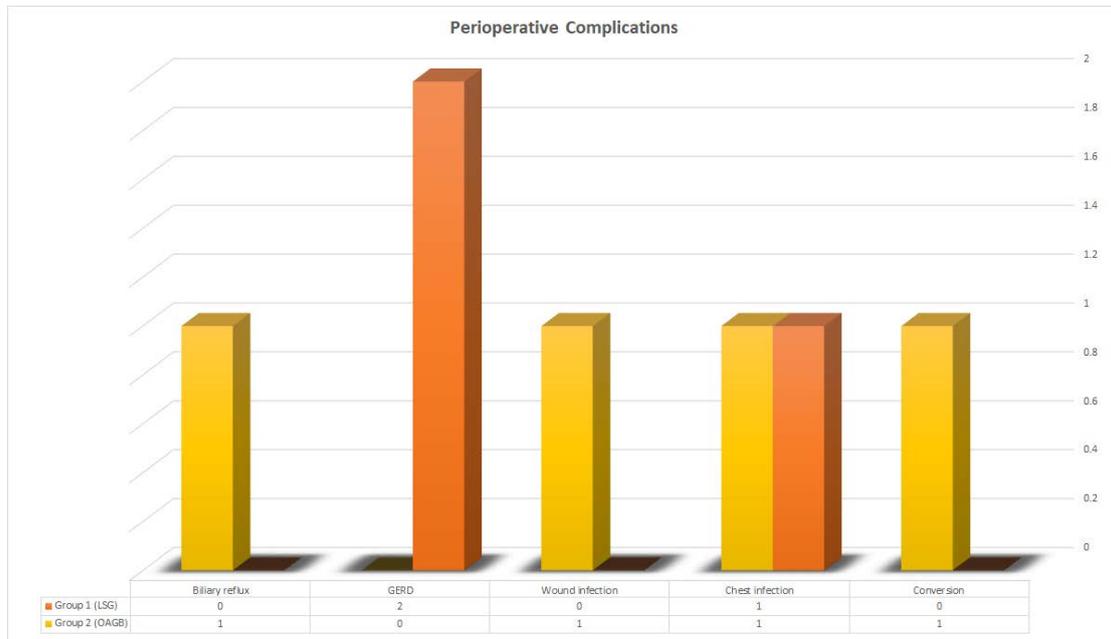


Figure (2): distribution of perioperative complications in both groups.

Patients in both groups showed good weight loss in the first year. A small difference was found between both groups in EWL% and total BMI loss after 1 year in favor of OAGB group but it was not statistically significant. Table (2) and figure (3) show the weight loss outcomes in both groups.

| | Group | | | | P value | Sig. |
|----------------|-------|------|-------|------|---------|------|
| | LSG | | OAGB | | | |
| | Mean | ±SD | Mean | ±SD | | |
| BMI baseline | 51.93 | 9.78 | 51.53 | 9.41 | 0.872* | NS |
| BMI 3 months | 44.00 | 8.49 | 43.93 | 7.94 | 0.975* | NS |
| BMI 6 months | 37.73 | 6.92 | 36.73 | 4.83 | 0.519* | NS |
| BMI 12 months | 33.47 | 5.69 | 31.87 | 3.66 | 0.200* | NS |
| Total BMI loss | 18.47 | 5.14 | 19.67 | 7.17 | 0.459* | NS |

*-Student t test.

Table (2): comparison between mean BMI and BMI loss in both groups.

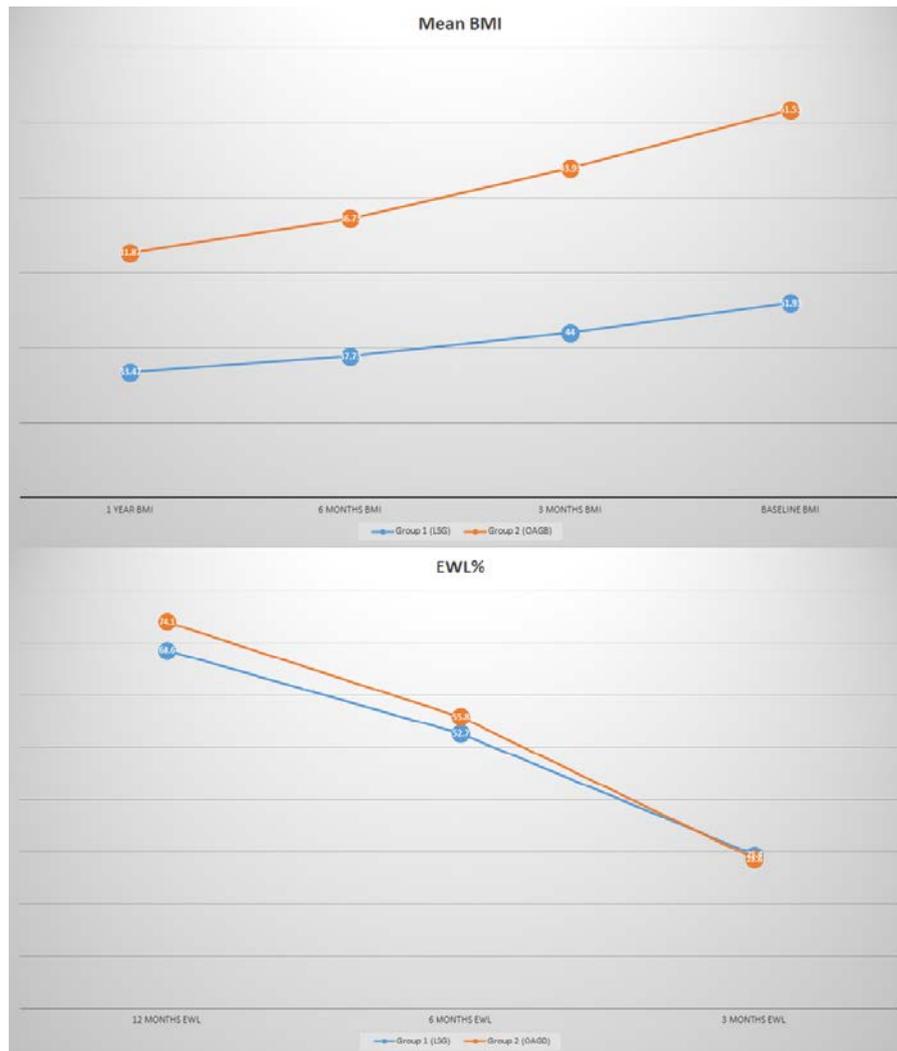


Figure (3): comparison between mean BMI and EWL% in both groups.

Regarding the postoperative DM biochemical outcomes, the mean FBS at 3,6 and 12 showed a none significant difference between both groups. At the same time, the total reduction in the FBS from the baseline after 12-month showed a statistically difference in the favor of group 2 (OAGB) (37.80 ± 6.41 mg/dl vs 29.93 ± 12.84 mg/dl, p value <0.004). The mean HbA1C as well as the total HbA1C drop showed a statistically significant difference in the favor of group 2 (OAGB) at all follow-up visits (3, 6 and 12 months). Both operations were effective in T2DM remission, however the effect of OAGB was seen earlier than LSG; at the 3-month follow up, with a mean HbA1c% of 6.84 ± 0.76 vs 7.35 ± 0.81 ($P = 0.014$). These results are shown in table (3) and figure (4).

| | Group | | | | P-value | Sig. |
|--------------------|--------|-------|--------|-------|---------|------|
| | LSG | | OAGB | | | |
| | Mean | ±SD | Mean | ±SD | | |
| FBS baseline | 145.27 | 12.78 | 149.67 | 12.27 | 0.179* | NS |
| FBS 3 months | 132.47 | 11.31 | 135.47 | 9.99 | 0.281* | NS |
| FBS 6 months | 124.20 | 10.99 | 125.07 | 10.66 | 0.758* | NS |
| FBS 12 months | 115.33 | 13.79 | 111.87 | 12.05 | 0.304* | NS |
| Total FBS change | 29.93 | 12.84 | 37.80 | 6.41 | 0.004* | HS |
| HbA1c baseline | 8.21 | .88 | 8.10 | .92 | 0.648* | NS |
| HbA1c 3 months | 7.35 | .81 | 6.84 | .76 | 0.014* | S |
| HbA1c 6 months | 6.70 | .71 | 6.21 | .71 | 0.009* | HS |
| HbA1c 12 months | 6.20 | .73 | 5.77 | .67 | 0.022* | S |
| Total HbA1c change | 2.01 | .59 | 2.33 | .48 | 0.024* | S |

*Student t test. -NS: none significant. – S: significant. – HS: Highly significant.

Table (3): Comparison between both groups regarding mean FBS & HbA1c values, and overall FBS & HbA1c change.

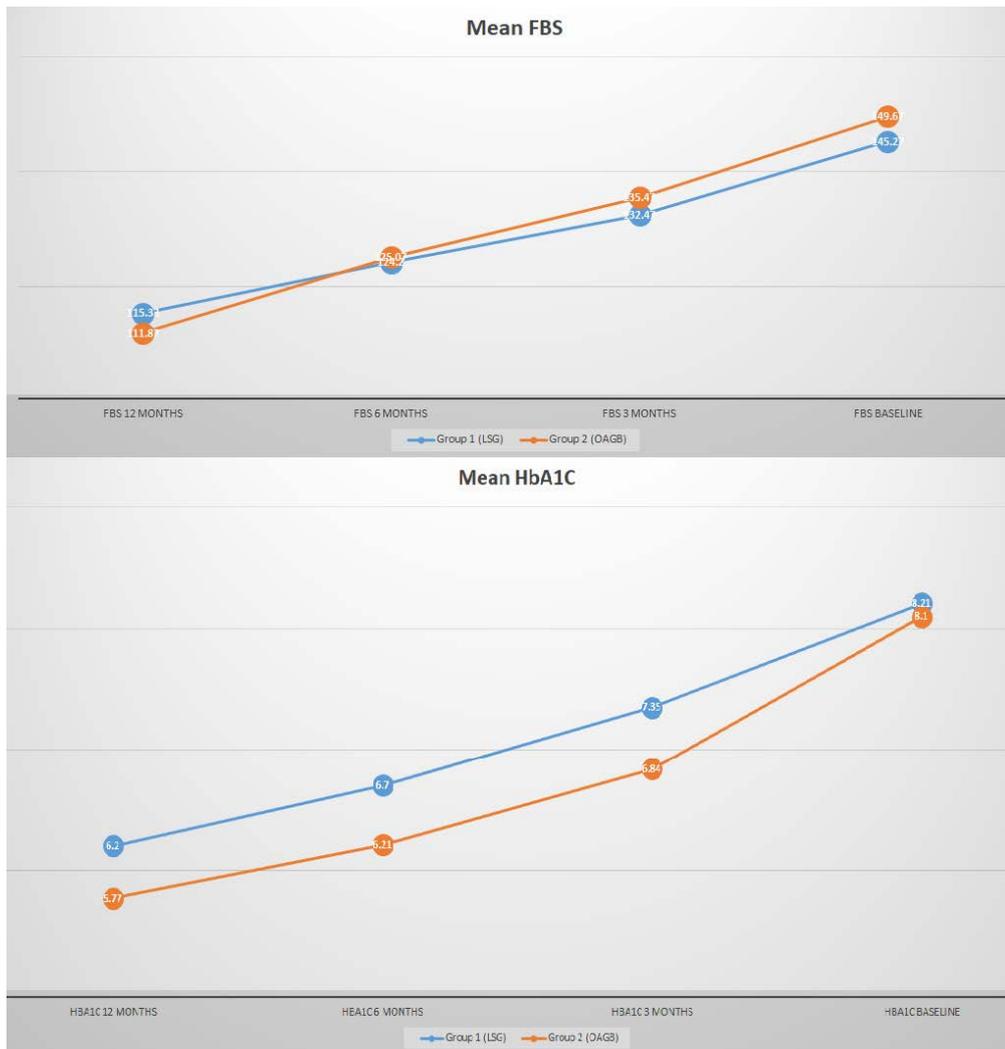


Figure (4): comparison between mean FBS and HbA1c in both groups.

Regarding the qualitative DM outcomes, there was a statistically significant difference in favor of OAGB group regarding the number of patients with totally resolved disease after 6 months (46.3% in group 2 Vs 20.7% in group 1, p-value = 0.028). After 12 months of follow-up. The number of totally resolved cases were 80% in group 2 versus 67.1% in group 1, the number of improved cases were 20.0% in group 2 versus 26.8% in group 1. 6.1% of patients in group 1 had no change in their DM status after 12 months in comparison with none of the patients in group 2. These differences were not large enough to be statistically significant as shown in table (4) and Figure (5).

| | | Group | | | | P value | Sig. |
|----------------------|-----------|-------|-------|------|-------|---------|------|
| | | LSG | | OAGB | | | |
| | | N | % | N | % | | |
| Resolved at 6 months | No | 65 | 79.3% | 43 | 53.7% | 0.028* | S |
| | Yes | 17 | 20.7% | 37 | 46.3% | | |
| Final outcome | No change | 5 | 6.1% | 0 | 00.0% | 0.331** | NS |
| | Improved | 22 | 26.8% | 16 | 20.0% | | |
| | Resolved | 55 | 67.1% | 64 | 80.0% | | |

-*Chi-square test. -**Fisher exact test. - NS: none significant. – S: significant.

Table (4): Comparison between both groups as regards DM outcome at 6 months and at final assessment.

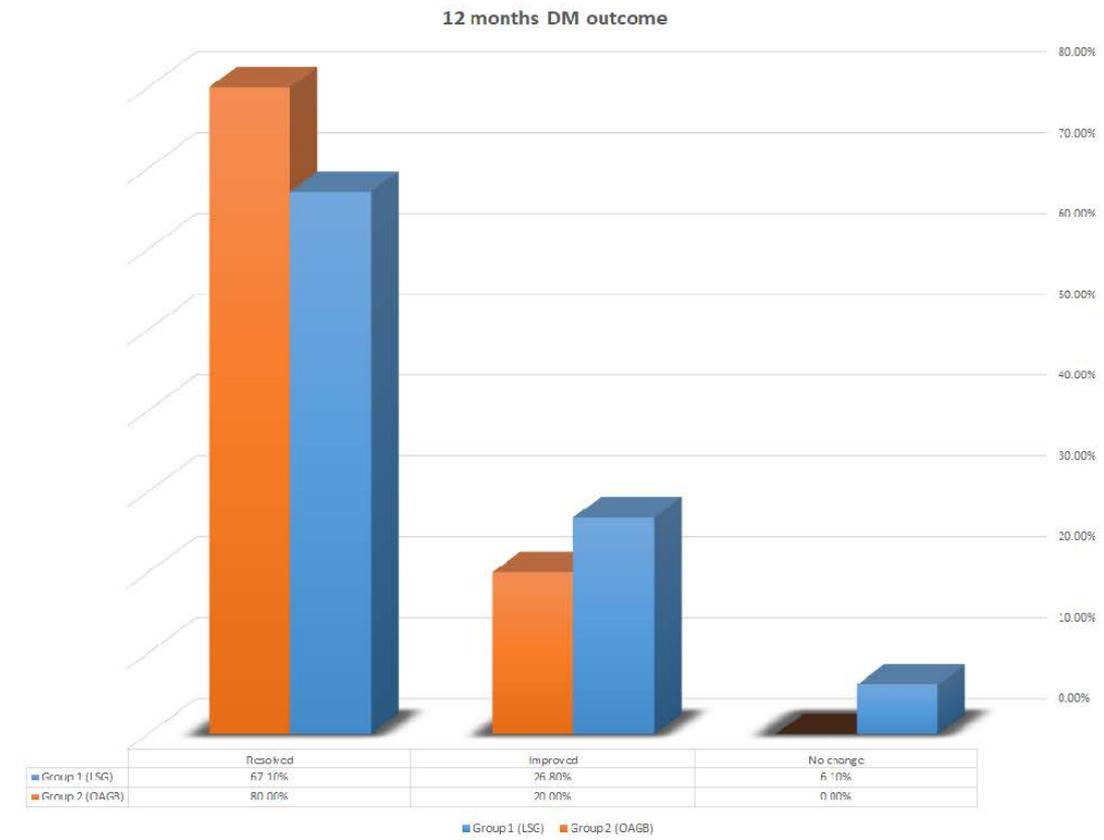
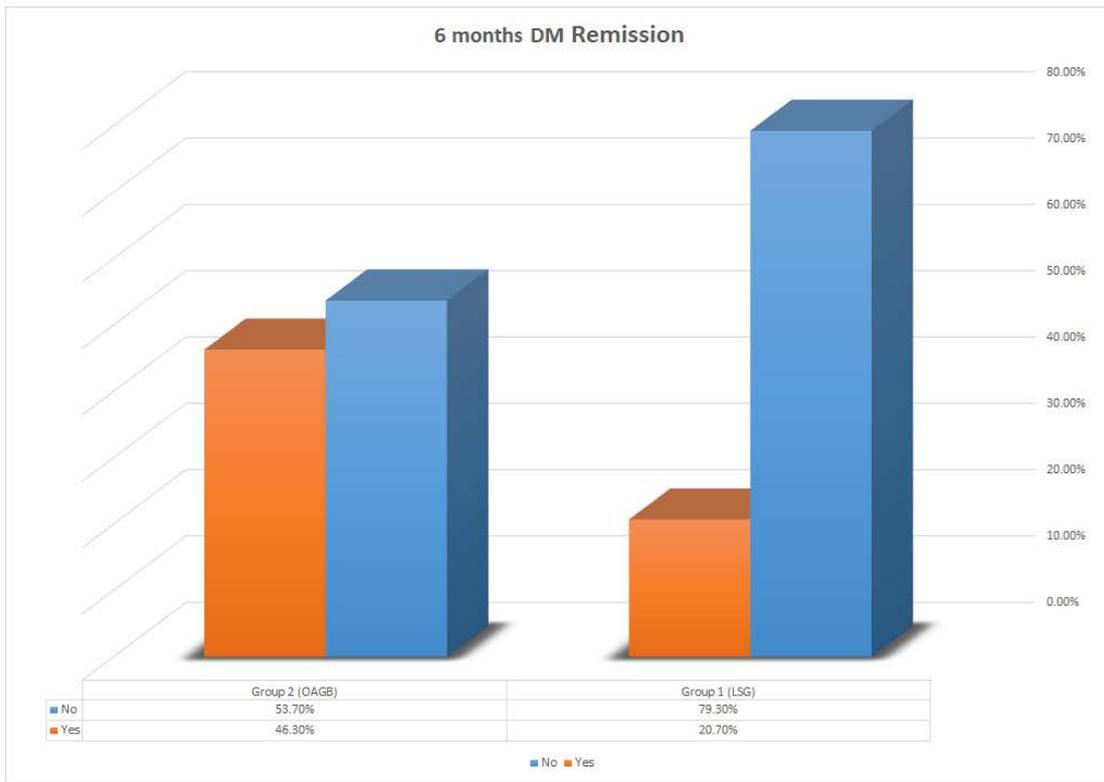


Figure (5): Comparison between both groups as regards DM outcome at 6 months and at final assessment.

To determine the predictors of DM remission at 12 months we divided the whole study population (162 patients) into 2 groups (completely resolved group and improved/no change group). A univariate comparative analysis was conducted on different preoperative parameters between both groups. We found a statistically significant difference between both groups regarding all the compared variables as shown in table (5) and figure (6).

| | Final outcome | | | | | P value | Sig. |
|--|----------------------|-------|-------|----------|--------|----------|------|
| | No change/improved | | | Resolved | | | |
| | Mean | ±SD | Mean | ±SD | | | |
| Age | 44.50 | 8.67 | 35.09 | 7.99 | 0.001* | HS | |
| C-peptide | 2.70 | 0.60 | 4.40 | 1.21 | 0.001* | HS | |
| HbA1c | 9.19 | 0.49 | 7.78 | 0.68 | 0.001* | HS | |
| | Final outcome | | | | | P value | Sig. |
| | No change/improved | | | Resolved | | | |
| | N | Row % | N | Row % | | | |
| Sex | Male | 5 | 8.5% | 54 | 91.5% | .0.019** | S |
| | Female | 38 | 36.9% | 65 | 63.1% | | |
| Family history | Negative | 0 | 0% | 54 | 100.0% | 0.001** | HS |
| | Positive | 43 | 39.8% | 65 | 60.2% | | |
| Preoperative medication | OHG | 5 | 4.4% | 108 | 95.6% | 0.001** | HS |
| | Insulin | 38 | 77.6% | 11 | 22.4% | | |
| Distribution of obesity | Peripheral | 21 | 65.6% | 11 | 34.4% | 0.001** | HS |
| | Central | 0 | 0% | 59 | 100.0% | | |
| | Both | 22 | 31% | 49 | 69% | | |
| Duration of DM (years) | <5years | 0 | 0% | 92 | 100% | 0.005** | HS |
| | >5years | 43 | 61.4% | 27 | 38.6% | | |
| Status of DM (according to baseline HbA1c) | Bad control > 8.5 % | 43 | 79.6% | 11 | 20.4% | 0.001** | HS |
| | Good control < 8.5 % | 0 | 0% | 108 | 100.0% | | |
| C-peptide | <3 ng/ml | 21 | 56.8% | 16 | 43.2% | 0.006*** | HS |
| | >3 ng/ml | 22 | 17.6% | 103 | 82.4% | | |

- *Student t test. - **Chi-square test. - ***Fisher exact test. – OHG: oral hypoglycemic.

Table (5): univariate analysis for predictors of DM remission.

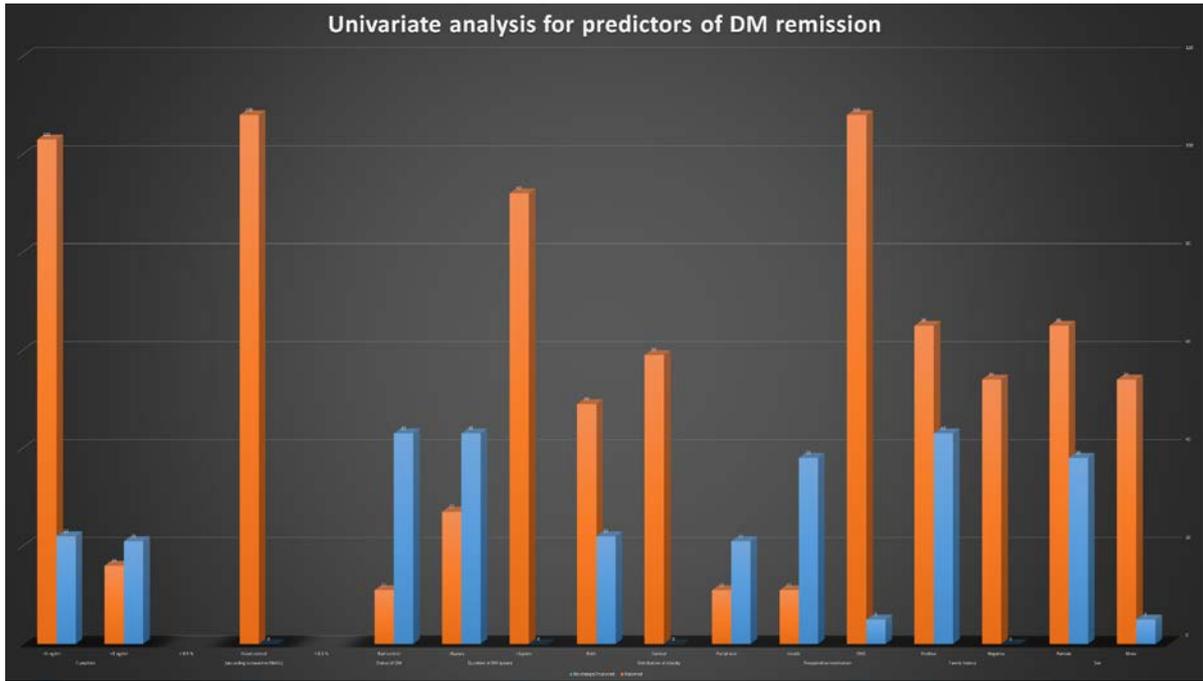


Figure (6): univariate analysis for predictors of DM remission.

Multivariate analysis was done for these parameters using logistic regression, to detect the independent predictors for DM resolution. It has shown that OHG use, preoperative C-peptide level >3 ng/ml, and DM duration <5 years correlated with a higher probability for complete remission of T2DM. So, OHG, C-peptide >3 ng/ml, and disease duration <5 years are considered independent significant predictors for T2DM remission as shown in table (6).

| | OR* | P value | Sig. | 95.0% Confidence interval for OR | |
|--------------------------|-------|---------|------|----------------------------------|---------|
| C-peptide >3 ng/ml | 5.667 | 0.017 | S | 0.310 | 103.452 |
| Disease duration <5 yrs. | 2.000 | 0.010 | S | 0.078 | 51.593 |
| OHG | 10.5 | 0.018 | S | 1.496 | 73.673 |

*adjusted odds ratio

Table (6): Regression model to study independent factors affecting T2DM remission.