

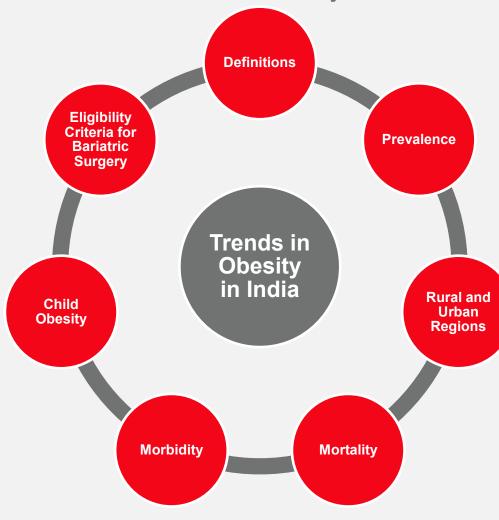
### Bariatric Surgery in India Evidence Summary Tool



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### **Obesity in India**

Click to find out more about obesity in India:



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 <sup>1</sup>WHO 2005

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 <sup>1</sup>Ebrahim 2010, Reddy 1998

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 In India, excessive weight gain is a growing health threat, with excess weight predicted to affect 22.5% of the population above 15 years old by 2015.<sup>1</sup>

Urbanization has been recognized as one of the most important factors promoting obesity emergence, due to an increased consumption of saturated fats and sugars as well as a sedentary lifestyle.<sup>2</sup>

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<sup>1</sup>De Onis 2014

<sup>2</sup>CDC 2012



Click to view more

information on definitions

of obesity

#### WHO Definitions in Adults and Children<sup>1</sup>

• The World Health Organization define excess weight and obesity in adults and children by absolute values of Body Mass Index (BMI).

	"Overweight"	"Obese"
Adults	BMI ≥ 25 kg/m <sup>2</sup>	BMI ≥ 30 kg/m²
Children	BMI exceeds WHO age-matched standard by 1 standard deviation	BMI exceeds WHO age-matched standard by > 2 standard deviations

#### **CDC Definitions in Children<sup>2</sup>**

• The Centers for Disease Control and Prevention defines "excess weight" and "obesity" in children according to the level of the child's development.

	"Overweight"	"Obese"
Children	BMI between 85 <sup>th</sup> and 90 <sup>th</sup> age- and sex- specific percentile	BMI exceeding 90 <sup>th</sup> percentile of matched population

Click to go back to

"Obesity in India"



India-specific Definitions of Obesity and Excess Weight

Asian Indians are at risk of obesity-related complications at lower levels of BMI when compared to Caucasians.<sup>1</sup>

Specific fat distribution (high truncal and abdominal adiposity) is associated with the influence on insulin sensitivity and other metabolic risk factors.<sup>2</sup>

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- A comparison of anthropometric measurements between Asian Indians and Caucasians show that Asian Indians have significantly greater total abdominal fat area, visceral fat area and truncal subcutaneous fat.<sup>3</sup>
- Compared to African-American patients with diabetes, Asian Indian patients have smaller waist circumference and waist-hip ratio, but comparable visceral fat volume.<sup>4</sup>

Asian Indians are more prone to lower glucose metabolism due to increased insulin resistance, and greater procoagulant tendency and dyslipidemia.<sup>5</sup>



1 Bhardwaj 2011, Misra 2005, Snehalatha 2003 2 Patel 2013 3 Chandalia 1999 4 Banerji 1997 5 Pandit 2012 Click to view more information on definitions of obesity India-specific Definitions of Obesity and Excess Weight

BMI has been recognized as the most appropriate measure of generalized obesity amongst Indians. Waist circumference, as a measure of abdominal obesity, should be assessed together with BMI for risk stratification of metabolic and cardiovascular diseases.<sup>1</sup>

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International and Asian-specific classifications of weight by BMI in adults:

Classification	WHO (International) <sup>2</sup>	WHO (Asia-Pacific) <sup>3</sup>	Consensus Statement for Asian Indians <sup>1</sup>
Underweight	< 18.5 kg/m²	< 18.5 kg/m²	-
Normal range	18.5-24.9 kg/m <sup>2</sup>	18.5-22.9 kg/m <sup>2</sup>	18.0-22.9 kg/m²
Normai range	10.5-24.9 Kg/III-	23.0-24.9 kg/m <sup>2</sup>	10.0-22.3 kg/III-
Overweight	> 25 kg/m²	> 25 kg/m²	23.0-24.9 kg/m <sup>2</sup>
Pre-obese	25-29.9 kg/m²	25.0-27.4 kg/m <sup>2</sup>	
Fie-obese		27.5-29.9 kg/m <sup>2</sup>	-
Obese I	<b>30-34.9</b> kg/m <sup>2</sup>	<b>30.0-32.4 kg/m</b> <sup>2</sup>	
Obese i	50-54.5 Kg/III-	<b>32.5-34.9 kg/m</b> <sup>2</sup>	
Obese II	35-39.9 kg/m²	35.0-37.4 kg/m²	> 25 kg/m²
Obese II		37.5-39.9	
Obese III	≥ 40 kg/m²	≥ 40 kg/m²	

Recommendations by the International Diabetes Federation (IDF) Taskforce on Epidemiology and Prevention of Diabetes:<sup>4</sup>

For Asian populations, classifications remain the same as the international classification but BMI cut-offs for public health action are set at 23, 27.5, 32.5 and 37.5 kg/m<sup>2</sup>.

 Coloured zones indicate BMI cut-offs for eligibility and prioritization of bariatric surgery. Yellow: Conditionally eligible but not prioritised for surgery.
 Green: Eligible and conditionally prioritised for surgery. Red: Eligible and prioritised for surgery. Conditions for conditional eligibility or prioritisation are: HbA1c > 7.5 despite fully optimised conventional therapy, especially if weight is increasing, or other weight-responsive comorbidities not achieving targets on conventional therapies (eg. blood pressure, dyslipidemia, obstructive sleep apnea).



<sup>1</sup>Misra 2009 <sup>2</sup>Adapted from WHO 2004 <sup>3</sup>Asian Consensus Meeting 2010, Yoon 2006 <sup>4</sup>IDF Taskforce Position Statement, Dixon 2011



#### **Trends in Prevalence**



An increasing number of both males and females in India are obese or overweight.

# Between 2005 and 2006

According to the National Family Health Surveys, 8.4% of men and 9.8% of women were overweight, and 1.3% of men and 2.8% of women were obese.<sup>1</sup>

# Between 2007 and 2010

The Study of Global Ageing and Adult Health surveys reported excess weight and obesity in 12% and 3% of Indian adults respectively.<sup>2</sup>

#### 2012

The National Nutrition Monitoring Bureau reported that 10% of Indian men and 13.5% of Indian women were obese or overweight.<sup>3</sup>

- □ Corresponding estimates reached almost 20% and 23.2% when excess weight was defined as BMI ≥ 23 kg/m<sup>2</sup>.<sup>3</sup>
- Abdominal obesity was reported in 13.6% of men (waist circumference ≥ 90 cm) and 30% of women (waist circumference ≥ 80 cm).<sup>3</sup>

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## **Distribution of Obesity by Region**



The distribution of obesity and excess weight varies greatly between regions and is particularly associated with the region's developmental status.



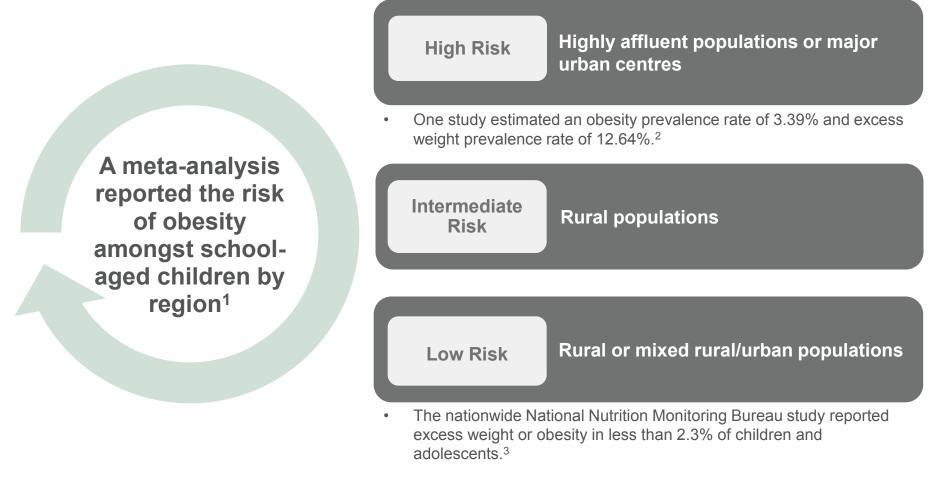
Percentage Males and Females with Excess Weight in Urban and Rural Regions

- The vast majority of Indians live in rural regions (68%).<sup>1</sup>
- The prevalence of excess weight in this population has been reported to be lower than that in urbanized regions (rural: 5.6-10% in men, 7.4-13.5% in women; urban: 15.9-28.6% in men, 23.5-34.3% in women).<sup>2</sup>
- When considering both sexes, 30.8% of the population in urban regions had a BMI of at least 25 kg/m<sup>2.2</sup>



#### Child Obesity in India





The interpretation of results of epidemiological studies is hindered by the differences with respect to participant age and definitions of health states (e.g. overweight, obesity).





### Morbidity of Obesity in India (1/3)



The WHO SAGE India study reported that the risk of Type 2 diabetes mellitus, hypertension and arthritis is increased by around 50% in overweight adults when compared to adults of normal weight.<sup>1</sup>

Condition	BMI (kg/m²)							
Condition	< 18.5	18.5 - 24.9	25.0 - 25.9	30.0-50.0				
		Prevalence (%)						
T2DM	2.0	2.9	8.8	5.1				
Hypertension	14.9	20.5	31.3	29.8				
Arthritis	7.6	9.3	18.2	9.1				
		Odds Ratio						
T2DM	0.52 [0.40, 0.68]	Reference Group	1.53 [1.21, 1.94]	2.24 [1.55, 3.21]				
Hypertension	0.66 [0.60, 0.74]	Reference Group	1.51 [1.31, 1.74]	1.40 [1.10, 1.79]				
Arthritis	0.78 [0.69, 0.89]	Reference Group	1.48 [1.25, 1.76]	1.17 [0.86, 1.60]				



Shaping T2DM=Type 2 diabetes mellitus the future <sup>1</sup>Shukla 2014

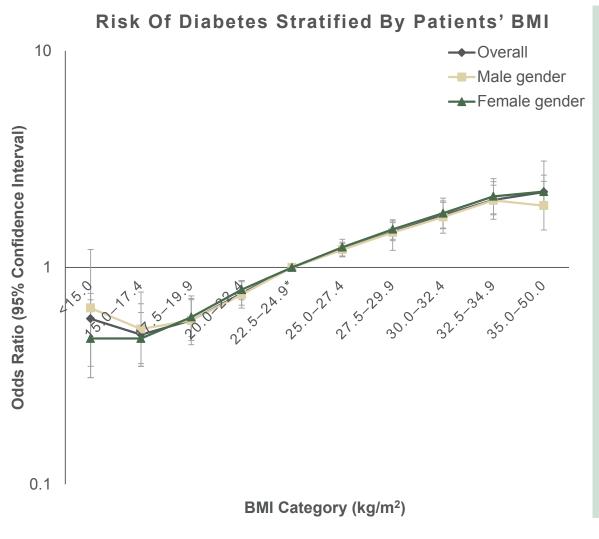


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### Morbidity of Obesity in India (2/3)



#### Type 2 Diabetes Mellitus



<sup>1</sup>Boffetta 2011

\*Reference group

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A large retrospective study representing 7 Asian countries (Japan, China, Taiwan, India, Bangladesh, Singapore and Korea) reported a 2.23-times increased risk of diabetes amongst morbidly obese patients (BMI  $\geq$  35 kg/m<sup>2</sup>) when compared to patients with BMI between 22.5-24.9 kg/m<sup>2</sup>.<sup>1</sup>

The overall prevalence rate of diabetes was 2.5% in the Indian population when adjusted for sex and age.<sup>1</sup>

Sex-stratified analysis demonstrated a higher prevalence of diabetes among men than women.<sup>1</sup>

> Click to view more information on morbidity of obesity in India

### Morbidity of Obesity in India (3/3)



#### \* Cardiovascular Disease

#### **Cardiovascular Disease**

- Obesity leads to a deregulation of metabolic pathways resulting in Type 2 diabetes mellitus, dyslipidemia, hypertension, elevated inflammatory markers and prothrombotic states – risk factors for cardiovascular disease.<sup>2</sup>
- Increased weight has been found to be an important determinant of cardiovascular risk in the Indian population.<sup>3</sup>

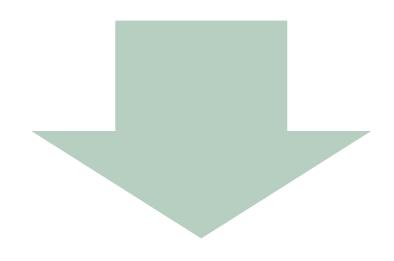
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<sup>1</sup>Poirier 2006 <sup>2</sup>Gothankar 2011, Gupta 2008, Singh 2011



### Mortality of Obesity in India





# According to Indian data, there is no strong evidence that obesity has an impact on mortality.

• The association between BMI and mortality in India is a reversed J-shape: more premature deaths occur in underweight people than in normal and overweight individuals.<sup>1</sup>

## In 1990, 32% of deaths in India were attributable to diet-related non-communicable diseases.

- This is only slightly lower than the overall mortality rate attributed to communicable diseases (particularly infections and and parasitic diseases), which are responsible for 43% of all deaths.
- A study of urban residents in Bombay showed that the risk of death due to circulatory system diseases is 30% higher in obese women as compared to individuals of normal weight. A similar trend has been observed in men.<sup>2</sup>





### Eligibility Criteria for Bariatric Surgery



Surgical therapy is considered when lifestyle changes and pharmacotherapy have failed to lower patient's BMI.

#### Lifestyle changes

(diet modification, physical activity, behavioural modification)

#### Pharmacotherapy

BMI criteria for initiation of pharmacotherapy after failing lifestyle changes:

	International Guidelines	Indian Guidelines
With comorbidities	≥ 27 kg/m²	≥ 25 kg/m²
No comorbidities	≥ 30 kg/m²	≥ 27 kg/m²

#### **Surgical Therapy**

BMI criteria for bariatric surgery after failing pharmacotherapy:

International Guidelines	Asian Guidelines	Indian Guidelines
<ul> <li>BMI ≥ 35 kg/m<sup>2</sup> with co-existing risk factors</li> <li>BMI ≥ 40 kg/m<sup>2</sup> regardless of comorbidities</li> </ul>	<ul> <li>≥ 27 kg/m<sup>2</sup> with comorbidities</li> <li>≥ 30 kg/m<sup>2</sup> without comorbidities</li> </ul>	<ul> <li>≥ 25 kg/m<sup>2</sup> with comorbidities</li> <li>≥ 27 kg/m<sup>2</sup> without comorbidities</li> </ul>





### **Bariatric Surgery in Indian Patients**

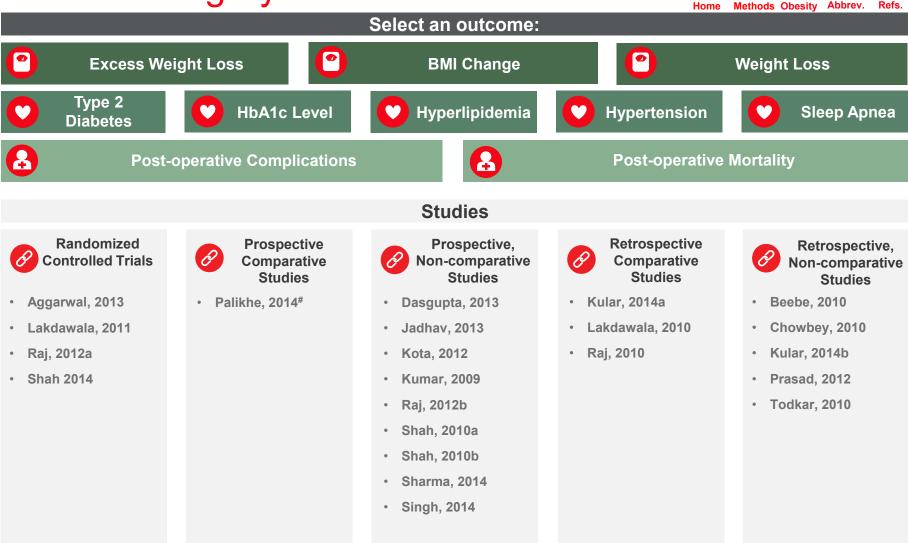
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Click to view the studies relevant to each outcome.
 Click to view baseline characteristics of the relevant studies.
 Click the name of each study to view the abstract.

\*This was a comparative study between bariatric procedures and conventional treatment (lifestyle modification, pharmacotherapy).

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Click to view comparative analyses between bariatric surgery and standard care in obesity

#### **Abbreviations**

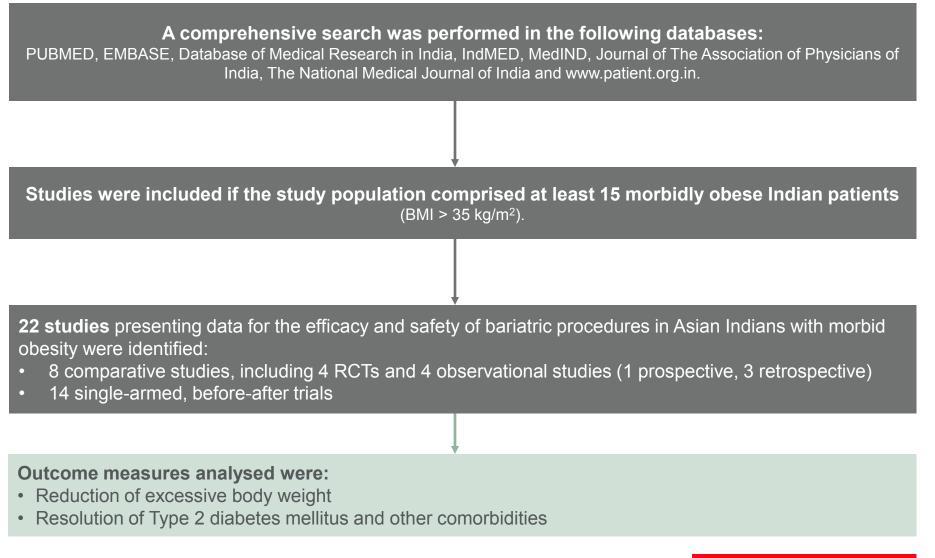


Abbreviation	Full Term
BMI	Body Mass Index
EWL	Excess Weight Loss
HbA1c	Glycosylated hemoglobin A1c
П	Ileal Interposition
LAGB	Laparoscopic adjustable gastric binding
LDJB	Laparoscopic Duodenal-jejunal Bypass
LMGB	Laparoscopic Mini Gastric Bypass
LRYGB	Laparoscopic Roux-en-Y Gastric Bypass
LSG	Laparoscopic Sleeve Gastrectomy
PDS-V	Polydioxanone V-shaped
SG	Sleeve Gastrectomy
SISG	Single Incision Sleeve Gastrectomy
T2DM	Type 2 Diabetes Mellitus



#### Systematic Literature Review Methods





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For more information, please contact Jayashree Mapari Health Economics & Market Access Manager jmapari@its.jnj.com, +91 2266646302 Click to view a summary of studies included for analysis

### **Studies Included for Analysis**



#### Overview of Studies Included for Analysis

- The studies represented a total number of 2,945 patients, ranging from 14 to 1,054 patients in individual studies.
- The follow-up period ranged from 1 month to 6 years; in the majority, the follow-up period was 1 or 2 years.
- One prospective, observational study compared LSG with intensive medical treatment (Palikhe 2014).

#### Baseline BMI

- 16 papers included only morbidly obese patients; however, the BMI cut-off differed among trials.<sup>1</sup>
- 2 trials also included non-obese patients (BMI < 30 kg/m<sup>2</sup>); however, the average baseline BMI indicated morbid obesity.<sup>2</sup>
- The remaining 4 studies did not specify inclusion criteria with respect to obesity severity; however, the average baseline BMI was higher than 40 kg/m<sup>2</sup>.<sup>3</sup>

#### Prevalence of Type 2 Diabetes Mellitus

- The prevalence of Type 2 diabetes mellitus ranged from 14% to 68% in 11 trials.<sup>4</sup>
- In the remaining 7 trials, only diabetic patients were assessed.<sup>5</sup>
- Baseline prevalence rate of metabolic syndrome was described in only one study (Todkar 2010).

#### Potential bias

- Some publications described studies performed in the same surgical center within a comparable time span and therefore had a high probability of sharing information on the same groups of patients.
- In order to minimize the possible risk of duplication bias in this analysis, only unique studies were combined together.



<sup>1</sup>Aggarwal 2013, Chowbey 2010, Dasgupta 2013, Kumar 2009, Lakdawala 2011, Prasad 2012, Shah 2010a, Shah 2010b, Jadhav 2013, Sharma 2014, Shah 2014, Singh 2014, Raj 2010, Raj 2012b, Todkar 2010; <sup>2</sup>Kota 2012, Palikhe 2014; <sup>3</sup>Beebe 2010, Lakdawala 2010, Kular 2014a, Kular 2014b; <sup>4</sup>Beebe 2010, Chowbey 2010, Kota 2012, Kular 2014a, Lukar 2014b, Lakdawala 2010, Lakdawala 2011, Prasad 2012. Raj 2012a, Shah 2014, Singh 2014; <sup>5</sup>Palikhe 2014, Kumar 2009, Dasgupta 2013, Shah 2010a, Shah 2010b, Raj 2012b, Todkar 2010

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### **Randomized Controlled Trials**



Study	Bariatric Procedure	N	BMI for inclusion (kg/m²)	Follow-up (months)	Baseline BMI <sup>1</sup> (kg/m <sup>2</sup> )	Patients with T2DM (%)
Aggarwal 2013	LSG (Staple line oversewing)	30	>40 or >35 with	12	<b>49.8 [37-72]</b> ª	-
	LSG	30	comorbidities		<b>49.3</b> [35-77] <sup>a</sup>	-
Lakdawala	LSG	50	<60	6	<b>43 [34-59]</b> <sup>b</sup>	16
2011	SISG	50	~00	0	<b>41 [32-58]</b> <sup>b</sup>	12
Raj 2012a	LRYGB LDJB+SG	29 28	>37 or >32 with comorbidities or >32 in obese patients unable to lose weight through conventional treatment	12	49.3 (3.6) 48.3 (3.8)	55 71
Shah 2014	LSG (Staple line reinforcement with PDS-V) LSG	51 49	>37.5 or >32.5 with ≥ 1 comorbidities	1	46.1 (8.5) 44.7 (9.8)	24 20
					\ /	



<sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated: (a) mean [range]; (b) median [range] PDS-V = Polydioxanone V-shaped

### **Prospective, Comparative Studies**



Study	Bariatric Procedure	N	BMI for inclusion (kg/m²)	Follow-up (months)	Baseline BMI <sup>1</sup> (kg/m²)	Patients with T2DM (%)
	LSG	14			40.5 (4.6)	100
Palikhe 2014	Intensive medical treatment	17	≥27.5	12.5	35.8 (5)	100



<sup>1</sup>BaselineBMI values are stated as mean (SD)

### Prospective, Non-comparative Studies

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Home	Methods	Obesity	Abbrev.	Refs.

Study	Bariatric Procedure	N	BMI for inclusion (kg/m²)	Follow-up (months)	Baseline BMI <sup>1</sup> (kg/m²)	Patients with T2DM (%)
Dasgupta 2013	LSG	38	>35	12	47.2 (7.4)	100
Jadhav 2013	LSG	42	>40	15	45 (5)	-
Kota 2012	II+SG	43	≥18.5	36	33.2 (7.8)	100
Kumar 2009	ll+SG	30	21-55	12	-	100
Raj 2012b	LDJB+SG	38	>37 or >32 with comorbidities or >32 if failed conventional treatment	12	42.3 (3.5)	68
Shah 2010a	LSG	53	>33	12	45.2 (9.3)	100
Shah 2010b	LSG	23	>33	24	40.7 (6.6)	100



<sup>1</sup>BaselineBMI values are stated as mean (SD)

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### Prospective, Non-comparative Studies Sudies Sudies Studies Stu

Study	Bariatric Procedure	Ν	BMI for inclusion (kg/m²)	Follow-up (months)	Baseline BMI <sup>1</sup> (kg/m²)	Patients with T2DM (%)
Sharma 2014	LSG	35	>40 or >35 with comorbidities	12	47.8	-
Singh 2014	LSG	100	≥35 or ≥30 with T2DM and ≥ 1 comorbidities	24	44.74 (7.16)	47



<sup>1</sup>BaselineBMI values are stated as mean (SD)

### **Retrospective, Comparative Studies**



Bariatric Procedure	N	BMI for inclusion (kg/m²)	Follow-up (months)	Baseline BMI <sup>1</sup> (kg/m²)	Patients with T2DM (%)
LMGB	104		60	44 (3.1)	60
LSG	118	-	60	42 (5.2)	52
LRYGB	50		10	<b>45.2 [32-66]</b> <sup>a</sup>	33
LSG	50	-	12	<b>46.0 [30-85]</b> <sup>a</sup>	14
LAGB	25		38	34.4	
LSG	108	>40 or	37	34.9	
LRYGB	340	comorbdities	42	45.3	-
LDJB+SG	38		9	36.6	
	Procedure LMGB LSG LSG LSG LSG LSG	ProcedureNLMGB104LSG118LRYGB50LSG50LSG108LSG340	ProcedureN(kg/m²)LMGB104-LSG118-LRYGB50-LSG50-LSG108>40 or > 35 with comorbdities	ProcedureN(kg/m²)(months)LMGB10460LSG118-LRYGB50-LSG50-LAGB2538LSG108>40 or >35 with comorbditiesLRYGB340comorbdities	Procedure         N         (kg/m²)         (months)         (kg/m²)           LMGB         104         60         44 (3.1)           LSG         118         60         42 (5.2)           LRYGB         50         -         12         45.2 [32-66] <sup>a</sup> LSG         50         -         12         46.0 [30-85] <sup>a</sup> LAGB         25         38         34.4           LSG         108         >40 or >35 with LRYGB         37         34.9           LRYGB         340         comorbdities         42         45.3



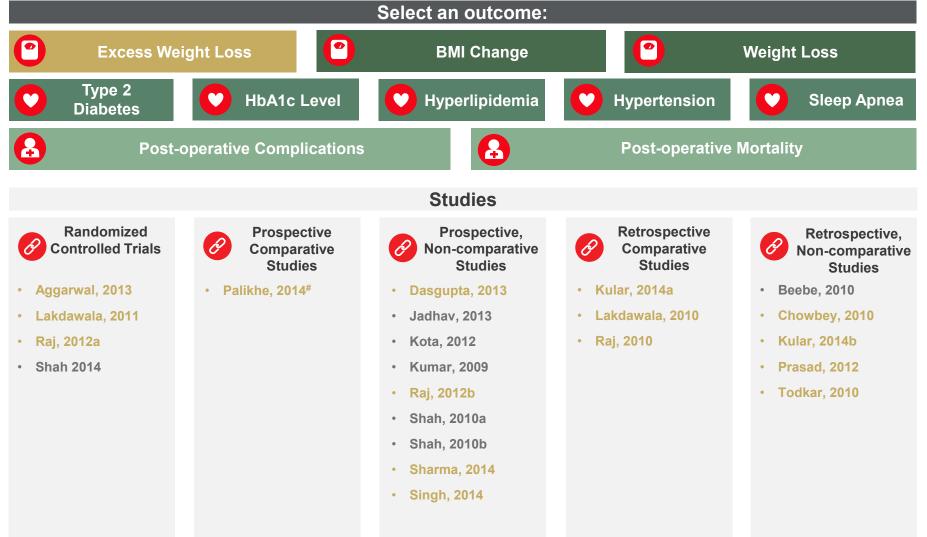
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Study	Bariatric Procedure	Ν	BMI for inclusion (kg/m²)	Follow-up (months)	Baseline BMI <sup>1</sup> (kg/m²)	Patients with T2DM (%)			
Beebe 2010	LAGB/ LRYGB/LSG	100	-	-	48.3 (7.8)	37			
Chowbey 2010	LSG	75	≥60 or 32.5-40 with comorbidities	≥6	58 [33.3-77.3] <sup>a</sup>	31			
Kular 2014b	LMGB	1054	-	72	43.2 (7.4)	64			
Prasad 2012	LSG	110	>40 or >35 with comorbidities; modified during the study to >37.5 or >32.5 with comorbidities	36	44.6 (6.8)	43			
Todkar 2010	LSG	23	>33	36	40.7 (6.6)	100			



#### **Excess Weight Loss**

# Home Methods Obesity Abbrev.



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"This was a comparative study between bariatric procedures and conventional treatment (lifestyle modification, pharmacotherapy).

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### Excess Weight Loss (1/2)

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Study	Bariatric	N	Baseline BMI	Excess Weight Loss (%)										
Sludy	Procedure	N	(kg/m <sup>2</sup> ) <sup>1</sup>	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.	24 mo.	36 mo.	42 mo.	48 mo.	60 mo.	72 mo.
Aggarwal	LSG (Staple line oversewing)	30	49.8 [37-72] <sup>c</sup>	-	43.0 (11)	59.0 (16)	-	74.0 (18)	-	-	-	-	-	-
2013	LSG	30	49.3 [35-77]⁰	-	45.0 (12)	61.0 (14)	-	72.0 (18)	-	-	-	-	-	-
Lakdawala 2011	LSG	50	43 [34-59] <sup>d</sup>	-	<b>32.6</b> <sup>d</sup>	<b>50.8</b> <sup>d</sup>	-	-	-	-	-	-	-	-
	SISG	50	41 [32-58] <sup>d</sup>	-	<b>33.4</b> <sup>d</sup>	<b>52.0</b> <sup>d</sup>	-	-	-	-	-	-	-	-
Raj 2012a	LRYGB	29	49.29 (3.6)	-	35.2 (5.3)	62.3 (6.3)	-	80.0 (4.8)	-	-	-	-	-	-
Palikhe 2014	LSG	14	40.5 (4.6)	-	-	-	-	61.2 (17.6) <sup>e</sup>	-	-	-	-	-	-
Dasgupta 2013	LSG	<b>38</b> ª	47.15 (7.4)	-	39.02 (9.09)	49.68 (11.8)	64 (19)	61.52 (15)	-	-	-	-	-	-
Raj 2012b	LDJB+ SG	38 <sup>b</sup>	42.3 (3.5)	-	34.2 (5.7)	60.7 (8.3)	-	71.8 (9.9)	74.1 (8.3)	-	-	-	-	-
Sharma 2014	LSG	32	47.8	-	22.7 (7.4)	38.8 (11.1)	50.0 (15.4)	64.3 (18.4)	-	-	-	-	-	-

"Excess weight loss (%)" refers to the excess weight lost following surgery, calculated as a percentage of the original excess weight. <sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated. (a) There were 36 and 35 patients followed up at 9 and 12 months; (b) Only 10 patients had follow-up period of 24-months; (c) Mean [range]; (d) Median [range]; (e) Mean duration of follow-up was 12.5-months

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### Excess Weight Loss (2/2)

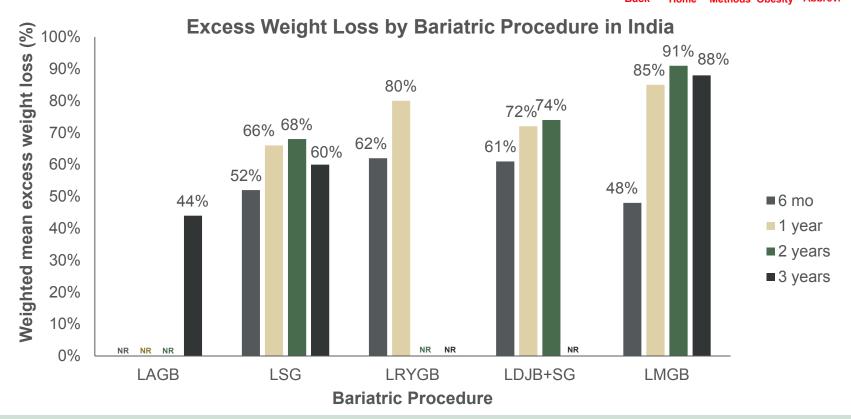


Study	Bariatric	N	Baseline BMI	Excess Weight Loss (%)										
Sludy	Procedure	N	(kg/m <sup>2</sup> ) <sup>1</sup>	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.	24 mo.	36 mo.	42 mo.	48 mo.	60 mo.	72 mo.
Singh 2014	LSG	100 <sup>a</sup>	44.74 (7.16)	23.3 (7.4)	37.7 (11.0)	51.0 (14.0)	-	62.4 (11.3)	67.7 (9.0)	-	-	-	-	-
Kular 2014a	LSG	118	42 (5.2)	-	-	-	-	69 (22.5)	66.2 (23.4)	61 (26.4)	-	56 (25)	51.2 (23)	-
Lakdawala 2010	LRYGB	50	45. 2 [32-66] <sup>e</sup>	-	-	<b>41.7</b> <sup>e</sup>	-	62.2 <sup>e</sup>	-	-	-	-	-	-
	LSG	50	46 [30-85]°	-	-	<b>50.8</b> <sup>e</sup>	-	<b>76.1</b> <sup>e</sup>	-	-	-	-	-	-
	LAGB	25	34.4	-	-	-	-	-	-	<b>44</b> 9	-	-	-	-
Raj 2010	LSG	108	34.9	-	-	-	-	-	-	<b>54</b> <sup>h</sup>	-	-	-	-
	LRYGB	340	45.3	-	-	-	-	-	-	-	84.0	-	-	-
Chowbey 2010	LSG	75 <sup>b</sup>	58.0 [33.3- 77.3] <sup>f</sup>	-	31.2	52.3	-	59.1	65.2	-	-	-	-	-
Kular 2014b	LMGB	1054 <sup>c</sup>	43.2 (7.4)	-	-	48	-	85	91	88	-	86	87	85
Prasad 2012	LSG	110 <sup>d</sup>	44.5 (6.8)	-	-	53.2 (11.8)	-	67.6 (13.0)	71.2 (13.9)	66.1 (14.3)	-	-	-	-
Todkar 2010	LSG	23	40.7 (6.6)	-	-	-	-	-	-	74.6	-	-	-	-



"Excess weight loss (%)" refers to the excess weight lost following surgery, calculated as a percentage of the original excess weight. 'Baseline BMI values are mean (SD) unless otherwise stated, (a) There were 80 and 24 patients followed up at 12 and 24 months; (b) There were 52 and 10 patients followed up at 12 and 24 months; (c) There were 54, 144, 265, 360, 481, 645 and 885 patients followed up at 6, 12, 24, 36, 48, 60 and 72 months; (d) There were 108, 80, 52 and 21 patients followed up at 6, 12, 24 and 38 months; (e) Median [range]; (f) Mean [range]; (g) Mean duration of follow-up was 38-months; (h) Mean duration of follow-up was 37-months Click to proceed to next page

#### 



Greatest weight loss at 6 months post-surgery was reported after LRYGB (62%) and LDJB+SG (61%).

At 1 year post-surgery, excess weight loss was greatest following bypass surgeries (LMGB, 85%; LRYGB, 80%).

At **2 years follow-up or longer**, the greatest reduction of excess weight was observed in patients who underwent LMGB (88-91%), which was noticeably more when compared to LDJB+SG (74%), LGG (60-68%) or LAGB (44%).



J&J India Value Dossier: Bariatric and Metabolic Surgery, 17 December 2015, Data on File "Excess weight loss (%)" refers to the excess weight lost following surgery, calculated as a percentage of the original excess weight. NR=Not reported

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#### Excess Weight Loss: Summary



"Excess weight loss" refers to the excess weight lost following surgery, calculated as a percentage of the original excess weight.

Excess weight loss was observed as soon as one month following surgery, with some studies reporting stable long-term effects at 4 to 6 years following surgery.

#### Short-term effects

- **Singh 2013** reported a 23% reduction in excess weight as soon as one month following surgery.
- Most studies reported a gradual reduction in excess weight over time, reaching 59–85% excess weight loss after 12 months and 65–91% excess weight loss after 24 months.

#### Stable long-term effects

- Prasad 2012 reported 70% reduction in excess weight 3 years after LSG.
- Kular 2014b reported 85% reduction in excess weight 12 months after LMGB, which remained almost unchanged 4 and 6 years after surgery (86% and 85% respectively).
- However, a study by **Kular 2014a** reported that while the effects of LSG in reducing excess weight were consistent between 12 and 24 months after surgery, this decreased thereafter.



### **BMI** Change

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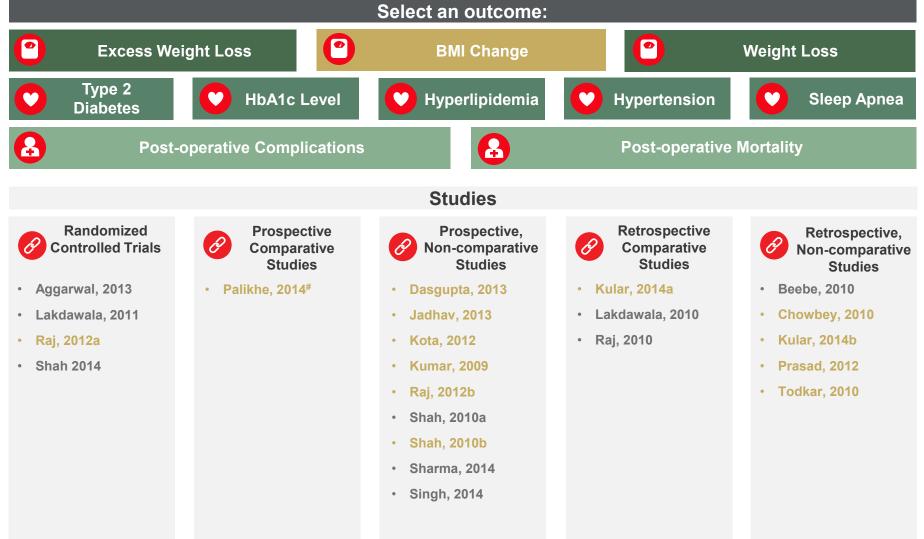
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"This was a comparative study between bariatric procedures and conventional treatment (lifestyle modification, pharmacotherapy).

### BMI Change (1/2)



	Bariatric		Baseline	Excess Weight Loss (%)											
Study	Procedur e	Ν	BMI (kg/m²) <sup>1</sup>	3 mo.	6 mo.	9 mo.	12 mo.	18 mo.	24 mo.	30 mo.	36 mo.	48 mo.	60 mo.	72 mo.	p- value²
Raj 2012a	LRYGB	29	49.29 (3.6)	9.0	15.9	-	20.5	-	-	-	-	-	-	-	-
Palikhe 2014	LSG	14	40.5 (4.6)	-	-	-	11.3 <sup>e</sup>	-	-	-	-	-	-	-	<0.001
Dasgupta 2013	LSG	<b>38</b> ª	47.15 (7.4)	8.8	13.9	17.0	15.3	-	-	-	-	-	-	-	<0.001
Jadhav 2013	LSG	42	45.0 (5)	7	-	15 <sup>d</sup>	-	-	-	-	-	-	-	-	-
Kota 2012	II+SG	43	33.2 (7.8)	5.3	7.6	-	6.7	6.4	7.7	7.3	6.6	-	-	-	<0.05
Kumar 2009	II+SG	30 <sup>b</sup>	33.8 (6.5) <sup>b</sup>	-	-	7.51	-	-	-	-	-	-	-	-	-
Raj 2012b	LDJB+ SG	38°	42.3 (3.5)	4.9	8.6	-	12.1	12.9	13.2	-	-		-	-	
Shah 2010b	LSG	23	40.7 (6.6)	-	-	-	-	-	9.8	-	-	-	-	-	-
Kular 2014a	LSG	118	42 (5.2)	-	-	-	13.3	-	12.8	-	11.5	9.4	7.6	-	

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<sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated <sup>2</sup>When compared to baseline (a) There were 36 and 35 patients followed up at 9 and 12 months; (b) Only 10 patients were analyzed; (c) There were 20 and 10 patients followed up at 18 and 24 months; (d) Duration of follow-up ranged between 9 and 15 months; (e) Click to proceed to next page

Mean duration of follow-up was 12.5 months

### BMI Change (2/2)



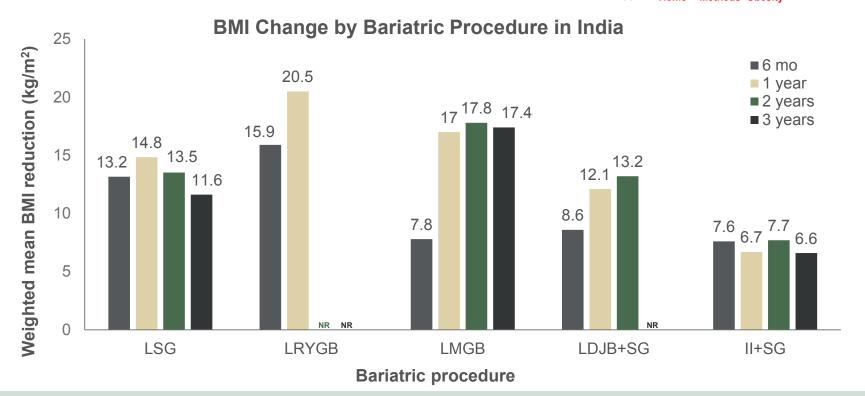
	Bariatric Procedur e	N	Baseline	Excess Weight Loss (%)											
Study			BMI (kg/m²) <sup>1</sup>	3 mo.	6 mo.	9 mo.	12 mo.	18 mo.	24 mo.	30 mo.	36 mo.	48 mo.	60 mo.	72 mo.	p- value <sup>2</sup>
Chowbey 2010	LSG	75 <sup>a</sup>	58.0 [33.3- 77.3] <sup>d</sup>	10.8	16.2	-	20.3	-	22.8	-	-	-	-	-	
Kular 2014b	LMGB	1054 <sup>b</sup>	43.2 (7.4)	-	7.8	-	17	-	17.8	-	17.4	17.2	17.3	17	-
Prasad 2012	LSG	110 <sup>c</sup>	44.5 (6.8)	-	10.8	-	14.0	-	15.0	-	14.3	-	-	-	
Todkar 2010	LSG	23	40.7 (6.6)	-	-	-	-	-	-	-	9.8	-		-	<0.001



<sup>2</sup>Baseline BMI values are mean (SD) unless otherwise stated <sup>1</sup>When compared to baseline (a) There were 52 and 10 patients followed up at 12 and 24 months; (b) There were 54, 144, 265, 360, 481, 645 and 885 patients followed up at 6, 12, 24, 36, 48, 60 and 72 months; (c) There were 108, 80, 52 and 21 patients followed up at 6, 12, 24 and 36 months; (d) Mean [range]

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### **BMI Change by Bariatric Procedure**



At **6 months post-surgery**, LRYGB and LSG recipients had the greatest mean BMI reduction (15.9 kg/m<sup>2</sup> and 13.2 kg/m<sup>2</sup> respectively).

At one year post-surgery, LRYGB recipients maintained the greatest mean BMI reduction (20.5 kg/m<sup>2</sup>).

From a **longer perspective (follow-up of at least 2 years)**, mean BMI reduction by LMGB, LDJB+SG and II+SG remained stable or decreased further between 1 and 2 years of follow-up. However, BMI reduction by LSG demonstrated a downward trend between the 1st and 3rd years of follow-up.



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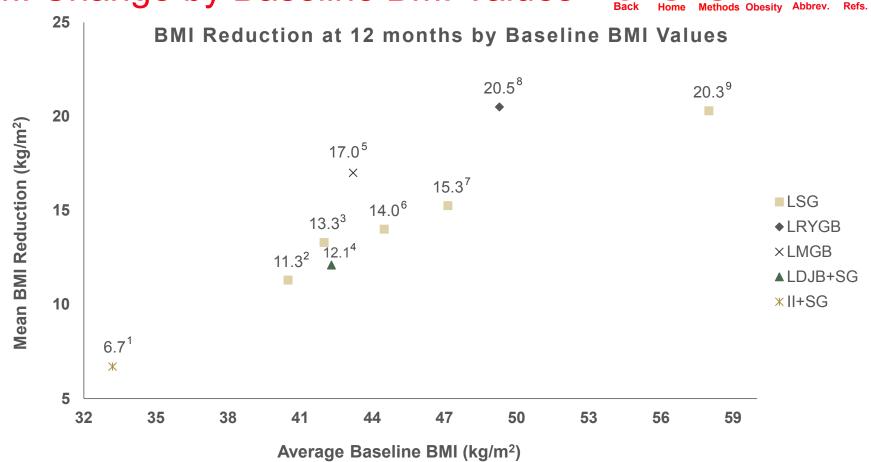
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Patients with greater mean BMI reductions at 12 months were also observed to have higher BMI values at baseline.



<sup>1</sup>Kota 2012; <sup>2</sup>Palikhe 2014; <sup>3</sup>Kular 2014a; <sup>4</sup>Raj 2012b; <sup>5</sup>Kular 2014b; <sup>6</sup>Prasad 2012; <sup>7</sup>Dasgupta 2013; <sup>8</sup>Raj 2012a; <sup>9</sup>Chowbey 2010 Click to proceed to Concluding Statement

### **BMI Change: Summary**



The majority of studies reported BMI reduction within 3 to 6 months of surgery, with some studies reporting long-term effects at 3 to 5 years following surgery.

#### Short-term effects

- 6 trials demonstrated a 4.9-10.8% reduction in BMI at 3 months post-surgery (4.9-11 kg/m<sup>2</sup>).<sup>1</sup>
- The magnitude of this effect gradually increased, with the greatest BMI reduction at 1 year post-surgery reported by **Raj 2012b** in patients who underwent LRYGB (20.5 kg/m<sup>2</sup>).

#### Long-term effects

- Data assessing the long-term efficacy of bariatric procedures was provided in 5 studies. Patients underwent LSG, LMGB and combined procedures, and were followed-up from 3 to 6 years.<sup>2</sup>
- Most of these studies demonstrated stable long-term effects of bariatric surgery:
  - Kular 2014b reported a mean BMI reduction of 17.4 kg/m<sup>2</sup> after 3 years and 17 kg/m<sup>2</sup> after 5 years following LMGB
  - Prasad 2012 reported a mean BMI reduction between 9.8-14.3 kg/m<sup>2</sup> after 3 years following LSG
  - Kota 2012 reported a mean BMI reduction BMI reduction of 6.6 kg/m<sup>2</sup> after 3 years following II+SG
  - However, the study by Kular 2014a reported that the efficacy of LSG in reducing BMI decreased in the long-term



#### Weight Loss

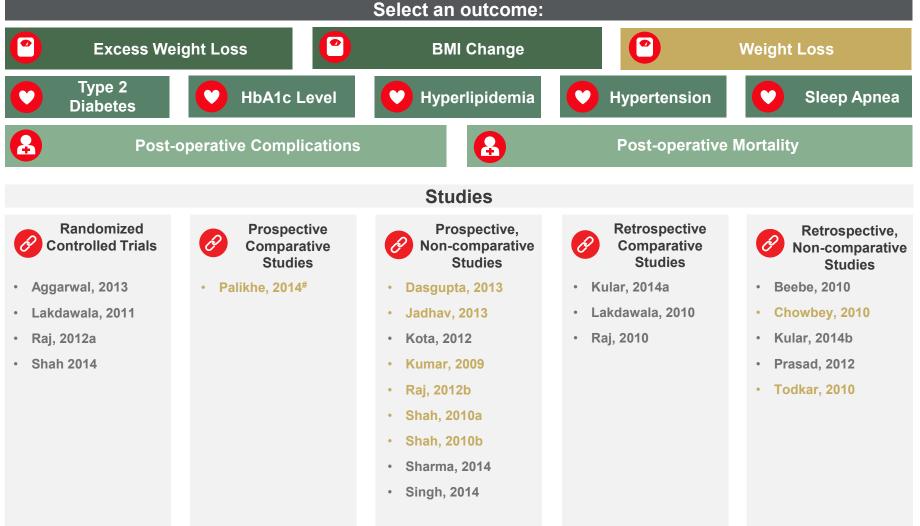
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"This was a comparative study between bariatric procedures and conventional treatment (lifestyle modification, pharmacotherapy).

#### Weight Loss

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Study	Bariatric	N	Baseline Ch	Weight Loss (kg)							
Sludy	Procedure	N	BMI (kg/m²) <sup>1</sup>	Weight (kg)	3 mo.	6 mo.	9 mo.	12 mo.	24 mo.	36 mo.	p-value
Palikhe 2014	LSG	14	40.5 (4.6)	99.5	-	-	-	28 <sup>f</sup>	-	-	<0.001
Dasgupta 2013	LSG	<b>38</b> ª	47.15 (7.4)	122.1	25.8	33.0	40.3	38.7			<0.001
Jadhav 2013	LSG	42	45.0 (5)	119	-	-	<b>26.7</b> <sup>e</sup>	-	-	-	0.00001
Kumar 2009	II+SG	<b>30</b> <sup>b</sup>	33.8 (6.5) <sup>b</sup>	91.4 (16.5) <sup>b</sup>	-	-	18.9	-	-	-	-
Raj 2012b	LDJB+SG	38	42.3 (3.5)	-	24.7 (3.1)	37.9 (5.8)	-	45.4 (8.3)	-	-	-
Shah 2010a	LSG	53	45.2 (9.3)	119.8	-	-	-	42.2 (18.6)	-	-	<0.001
Shah 2010b	LSG	23	40.7 (6.6)	104.1 (22.2)	-	-	-	-	26.9	-	-
Chowbey 2010	LSG	75 <sup>c</sup>	58.0 [33.3-77.3] <sup>d</sup>	149.6	49.2	67.9	-	77.6	75.6	-	-
Todkar 2010	LSG	23	40.7 (6.6)	104.1	-	-	-	-	-	26.9	<0.001

<sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated

(a) There were 36 and 35 patients followed up at 9 and 12 months; (b) Only 10 patients were analyzed; (c) There were 52 and 10 patients followed up at 12 and 24 months; (d) Mean [range]; (e) Duration of follow-up ranged between 9 and of surgery 15 months; (f) Mean duration of follow-up was 12.5 months

## Weight Loss: Summary



Weight loss was associated with patients' severity of obesity (BMI) at baseline.

### Baseline BMI values and weight loss post-surgery

- **Chowbey et al. 2010** enrolled patients with the highest mean baseline BMI (58 kg/m<sup>2</sup>). Following LSG, patients reported weight reductions of up to 49 kg and 78 kg at 3 and 12 months post-surgery respectively.
  - A smaller magnitude of weight loss was observed in 6 other LSG studies that reported lower baseline BMI values (mean weight loss of 26-49 kg and 28-42 kg at 3 and 12 months respectively following LSG).<sup>1</sup>
- **Raj 2012b** reported a mean baseline BMI of 42.3 kg/m<sup>2</sup>. Mean weight loss in this study was 25 kg at 3 months and 45 kg at 12 months post-LDJB+SG.
- Kumar 2009 enrolled patients with the lowest mean baseline BMI (33.8 kg/m<sup>2</sup>) and reported weight loss of 18.9 kg at 9 months following II+SG.



## **Type 2 Diabetes Mellitus**

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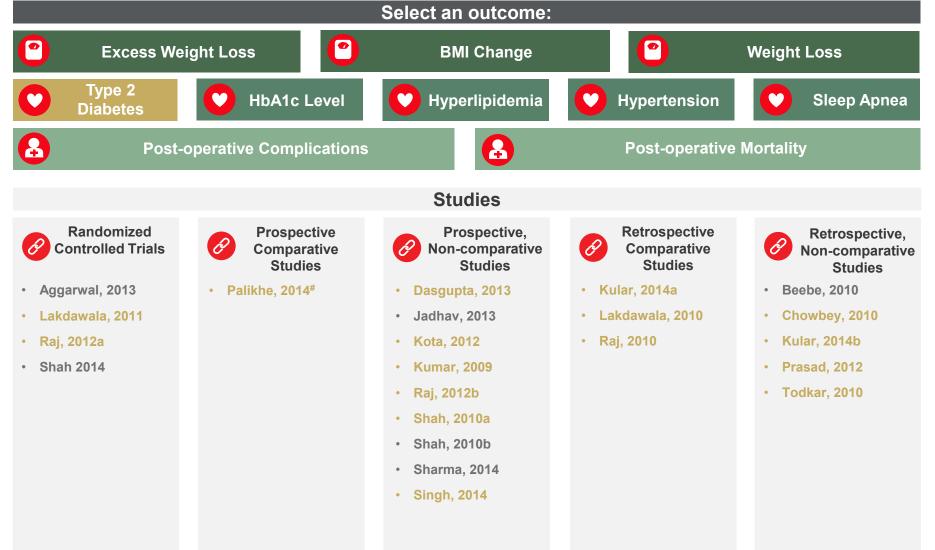
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\*This was a comparative study between bariatric procedures and conventional treatment (lifestyle modification, pharmacotherapy).

## Type 2 Diabetes Mellitus (1/2)



Study	Baseline BMI					Resolu	tion of T2	:DM (%)						
Sludy	Procedure	N	(kg/m²) <sup>1</sup>	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.	18 mo.	24 mo.	30 mo.	36 mo.	60 mo.	72 mo.
Lakdawala	LSG	8	43 [34-59] <sup>b</sup>	-	-	75	-	-	-	-	-	-	-	
2011	SISG	6	41 [32-58] <sup>b</sup>	-	-	83	-	-	-	-	-	-	-	-
Raj 2012a	LRYGB	16	49.3 (3.6)	-	-	-	-	81	-	-	-	-	-	-
Palikhe 2014	LSG	14	40.5 (4.6)	-	-	29	-	36	-	-	-	-	-	-
Dasgupta 2013	LSG	35	47.15 (7.4)	-	-	-	-	77	-	-	-	-	-	-
Kota 2012	II+SG	<b>43</b> <sup>a</sup>	33.2 (7.8)	-	48	48	-	61	55	79	50	60	-	-
Kumar 2009	II+SG	30	33.8 (6.5) <sup>c</sup>		-	-	<b>70</b> °	77	-	-	-	-	-	-
Raj 2012b	LDJB+SG	26	42.3 (3.5)	-	-	-	-	73	-	-	-	-	-	-
Shah 2010a	LSG	53	45.2 (9.3)	81 <sup>d</sup>	-	-	-	96	-	-	-	-	-	-
Singh 2014	LSG	47	44.74 (7.2)	-	-	64	-	77	-	83	-	-	-	-
Kular	LSG	61	42 (5.2)	-	-	-	-	-	-	-	-	-	81	-
2014a	LMGB	63	44 (3.1)	-	-	-	-	-	-	-	-	-	92	-



<sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated

(a) There were 42, 42, 36, 22, 14, 8 and 5 patients followed up at 3, 6, 12, 18, 24, 30 and 36 months;
(b) Median [range]; (c) Only 10 patients were analyzed; (d) Analysis for 1 month post-surgery includes only 48 patients who used anti-diabetic medication

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## Type 2 Diabetes Mellitus (2/2)



Study	Bariatric	N	Baseline BMI					Resolu	ition of T2	2DM (%)				
Sludy	Procedure	N	(kg/m²) <sup>1</sup>	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.	18 mo.	24 mo.	30 mo.	36 mo.	60 mo.	72 mo.
Lakdawala	LRYGB	17	45. 2 [32-66]⁵	-	-	98	-	100	-	-	-	-	-	-
2010	LSG	7	46 [30-85]⁵	-	-	79	-	98	-	-	-	-	-	-
	LAGB	-	34.4	-	-	-	-	-	-	-	-	<b>20</b> <sup>d</sup>	-	-
Raj 2010	LSG	-	34.9	-	-	-	-	-	-	-	-	<b>21</b> <sup>e</sup>	-	-
	LRYGB	-	45.3	-	-	-	-	-	-	-	-	89 <sup>f</sup>	-	-
Chowbey 2010	LSG	<b>23</b> ª	58.0 [33.3-77.3]℃	-	74	83	-	81	-	75	-	-	-	-
Kular 2014b	LMGB	674	43.2 (7.4)	-	-	-	-	-	-	-	-	-	-	93
Prasad 2012	LSG	47	44.5 (6.8)		-	68	-	81	-	86	-	83	-	-
Todkar 2010	LSG	23	40.7 (6.6)	-	-	-	-	-	-	-	-	73	-	-



<sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated

(a) There were 52 and 10 patients from whole sample followed up at 12 and 24 months; (b) Median [range]; (c) Mean [range]; (d) Mean duration of follow-up was 38 months; € Mean duration of follow-up was 37 months; (f) Mean duration of follow-up was 42 months

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# Type 2 Diabetes Mellitus: Summary



Resolution of Type 2 diabetes mellitus was defined in most studies as normalized fasting glucose levels and glycosylated hemoglobin (HbA1c) without the need for anti-diabetic medications.<sup>1</sup> Cut-off points for HbA1c and fasting plasma glucose levels varied between trials.

Nonetheless, the majority of studies reported resolution of Type 2 diabetes mellitus at 1 year post-surgery, with long-term effects reported up to 6 years following surgery.

### Short-term Effects

• Type 2 diabetes mellitus resolved in 36-100% of patients at 1 year post-surgery.

### Long-term effects

- 6 trials reported the resolution of Type 2 diabetes mellitus (T2DM) amongst patients beyond 1 year of follow-up:
  - Kular 2014a and Kular 2014b reported resolution of T2DM in 92% and 93% of patients at 5 and 6 years post-LMGB
  - Kota 2012 reported resolution of T2DM in 60% of patients at 3 years post-II+SG
  - **Prasad 2012** and **Todkar 2010** reported resolution of T2DM in 73-83% of patients 3 years following LSG
    - However, Raj 2010 reported lower rates of T2DM resolution following LSG (21% of patients)



## HbA1c Level

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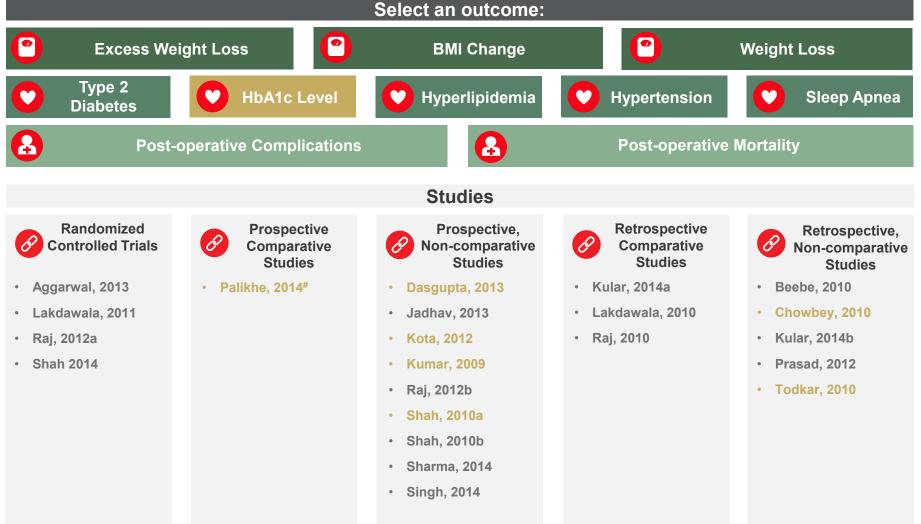
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\*This was a comparative study between bariatric procedures and conventional treatment (lifestyle modification, pharmacotherapy).

## HbA1c Level: Summary



	Deviatria		Baseline Cha	racteristics	Change in HbA1c (%)								
Study	Bariatric Procedure	N	BMI (kg/m²) <sup>1</sup>	HbA1c (%)	3 mo.	6 mo.	9 mo.	12 mo.	18 mo.	24 mo.	30 mo.	36 mo.	p-value
Palikhe 2014	LSG	14	40.5 (4.6)	8.5	-	-	-	-1.8 <sup>d</sup>	-	-	-	-	<0.001
Dasgupta 2013	LSG	38	47.15 (7.4)	7.8	-1.4	-1.6	-1.8	-2.0	-	-	-	-	<0.001
Kota 2012	II+SG	43	33.2 (7.8)	9.6 (2.1)	-2.8	-2	-	-2.5	-2.3	-3.2	-2.7	-2.4	
Kumar 2009	II+SG	<b>30</b> <sup>a</sup>	-	10.1 (2.2)	-	-	-3.4	-	-	-	-	-	-
Shah 2010a	LSG	53	45.2 (9.3)	8.4	-	-	-	-2.3	-	-	-	-	<0.001
Chowbey 2010	LSG	<b>75</b> <sup>b</sup>	58.0 [33.3-77.3] <sup>c</sup>	6.5	-0.1	-1.3	-	-1.7	-	-1.5	-	-	-
Todkar 2010	LSG	23 <sup>c</sup>	40.7 (6.6)	9.1	-	-	-	-	-	-	-	-2.7	

All studies reported an improvement in HbA1c between 1 and 3 years following surgery. In 3 studies, the change in HbA1c was also reported as statistically significant.<sup>2</sup>

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<sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated <sup>2</sup>Dasgupta 2013, Palikhe 2014, Shah 2010a (a) Baseline measurement of HbA1c was presented only for 10 patients; (b) There were 52 and 10 patients followed up at 12 and 24 months; (c) Median [range]; (d) Mean duration 12.5 (5) months

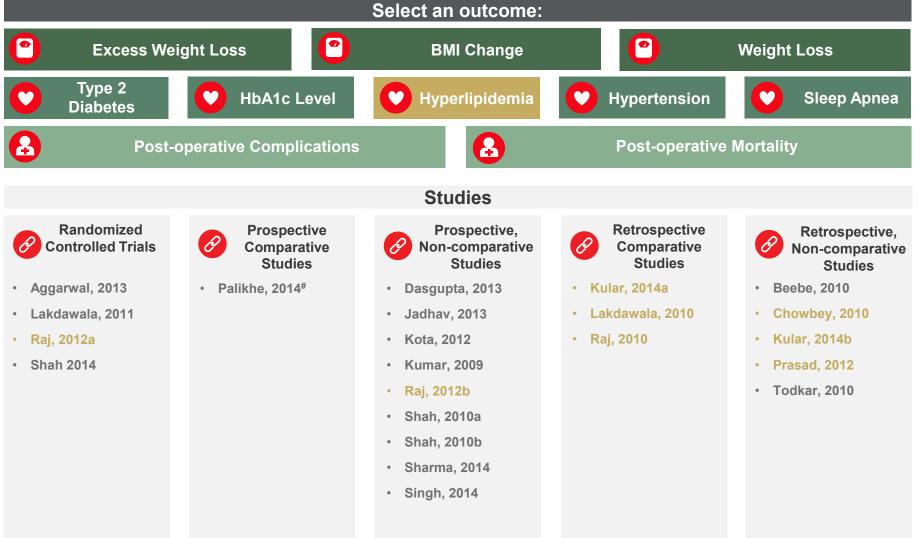
## Hyperlipidemia

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treatment (lifestyle modification, pharmacotherapy)

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## Hyperlipidemia



Study	Bariatric Procedur	N	Baseline BMI	Patients with HLD at			Patient	ts with HLD	Post-surg		Methods		Resolution
Siddy	e	N	(kg/m²) <sup>1</sup>	Baseline (%)	3 mo.	6 mo.	12 mo.	24 mo.	30 mo.	36 mo.	60 mo.	72 mo.	Rate (%)
Raj 2012a	LRYGB	29	49.3 (3.6)	62	-	0	-	-	-	-	-	-	100
Raj 2012b	LDJB +SG	38	42.3 (3.5)	58	-	8	-	-	-	-	-	-	86
Kular 2014a	LSG	118	42 (5.2)	54	-	-	-	-	-	-	7	-	72
Kulai 2014a	LMGB	104	44 (3.1)	63	-	-	-	-	-	-	6	-	90
Lakdawala	LRYGB	50	45.2 [33-66]ª	-	-	-	-	-	-	-	-	-	<b>78</b> c,i
2010	LSG	50	46.0 [30-85]ª	-	-	-	-	-	-	-	-	-	75 <sup>c,i</sup>
	LAGB	25	34.4	-	-	-	-	-	-	-	-	-	<b>30</b> <sup>d,i</sup>
Raj 2010	LSG	108	34.9	-	-	-	-	-	-	-	-	-	<b>34</b> <sup>e,i</sup>
	LRYGB	340	45.3	-	-	-	-	-	-	-	-	-	88 <sup>f,i</sup>
Chowbey 2010	LSG	75	58 [33.3-77.3]ª	83	36	16	12	10	-	-	-	-	<b>88</b> g
Kular 2014b	LMGB	1,054	43.2 (7.4)	62	-				<b>6</b> <sup>b</sup>				91
Prasad 2012	LSG	110	44.5 (6.8)	38	-	13	-	-	-	-	-	-	86 <sup>h</sup>



HLD=hyperlipidemia. <sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated. (a) Median [range]; (b) Result reported for 6 to 72 months post-surgery; (c) Resolution rate at 12 months post-surgery; (d) Resolution rate at 38 months post-surgery; (e) Resolution rate at 37 months post-surgery; (f) Resolution rate at 42 months post-surgery; (g) Resolution rate at 24 months post-surgery; (h) Resolution rate at 36 months post-surgery; (h) Resolution rate at 24 months post-surgery; (h) Resolution rate at 24 months post-surgery; (h) Resolution rate at 36 months post-surgery; (h) Resolut

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# Hyperlipidemia: Summary



The majority of studies reported resolution of hyperlipidemia at 1 year post-surgery, with long-term effects reported up to 6 years following surgery.

### Short-term Effects

- Chowbey 2010 reported that hyperlipidemia resolved in 57% of patients at 3 months following LSG.
- At 6 to 12 months of follow up, hyperlipidemia resolution were reported in:
  - 67-85% of patients following LSG
  - 78-100% of patients following LRYGB
  - 86% of patients following LDJB+SG

### Long-term effects

- Beyond 1 year of follow-up, hyperlipidemia resolution were reported in:
  - 90-91% of patients, up to 6 years following LMGB
  - 34-88% of patients, 2 to 5 years following LSG
  - 30% of patients, over 3 years following LAGB
  - 88% of patients, over 3 years following LRYGB
- Small sample sizes in the respective studies may have contributed to the relatively low efficacy of LAGB<sup>1</sup> and the inconsistent results for LSG.<sup>2</sup>

## **Hypertension**

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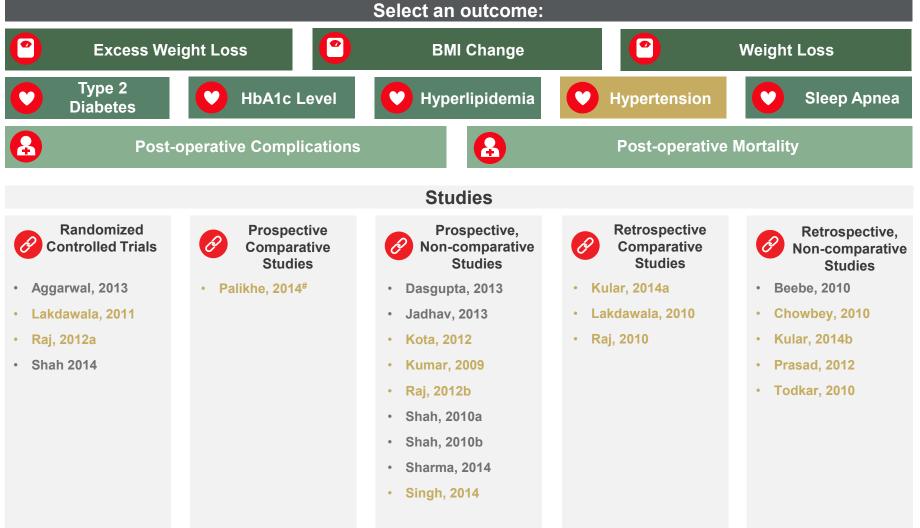
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\*This was a comparative study between bariatric procedures and conventional treatment (lifestyle modification, pharmacotherapy).

## Hypertension (1/2)



Study	Bariatric	N	Baseline	Patients	Patients Patients with HTN Post-surgery (%) ith HTN at							,		Resolution Rate (%)
Sludy	Procedure	N	BMI (kg/m²) <sup>1</sup>	Baseline (%)	3 mo.	6 mo.	12 mo.	18 mo.	24 mo.	30 mo.	36 mo.	60 mo.	72 mo.	Rate (%)
Lakdawala	LSG	50	<b>43 [34-59]</b> <sup>a</sup>	10	-	4	-	-	-	-	-	-	-	60
2011	SISG	50	<b>41 [32-58]</b> ª	14	-	6	-	-	-	-	-	-	-	57
Raj 2012a	LRYGB	29	49.3 (3.6)	41	-	-	10	-	-	-	-	-	-	75
Palikhe 2014	LSG	14	40.5 (4.6)	100	-	-	<b>71</b> <sup>b</sup>	-	-	-	-	-	-	29
Kota 2012	II+SG	43	33.2 (7.8)	70	-	-	-	-	-	-	7	-	-	<b>90</b> °
Kumar 2009	II+SG	30	-	100	-	-	10	-	-	-	-	-	-	<b>90</b> <sup>d</sup>
Raj 2012b	LDJB +SG	38	42.3 (3.5)	42	-	-	13	-	-	-	-	-	-	69
Singh 2014	LSG	100	44.74 (7.2)	56	-	33	20	-	13	-	-	-	-	77°
Kular	LSG	118	42 (5.2)	47	-	-	-	-	-	-	-	35	-	74
2014a	LMGB	104	44 (3.1)	58	-	-	-	-	-	-	-	44	-	76
Lakdawala	LRYGB	50	45.2 [33-66] <sup>a</sup>	28	-	-	-	-	-	-	-	-	-	<b>95</b> <sup>f,g</sup>
2010	LSG	50	46.0 [30-85]ª	8	-	-	-	-	-	-	-	-	-	<b>91</b> <sup>f,g</sup>



HTN=hypertension. 'Baseline BMI values are mean (SD) unless otherwise stated. (a) Median [range]; (b) Follow-up at 12.5 months post-surgery; (c) Resolution rate at 36 months post-surgery; (d) Resolution rate was also reported at 9.1 months post-surgery; (10 patients were analysed with 100% resolution rate); (e) Resolution rate at 24 months post-surgery; (f) Resolution rate at 22 months post-surgery; (f) Resolution rate at 22 months post-surgery; (g) The study reported resolution rates but not the percentage of patients with HLD at the respective time points

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## Hypertension (2/2)



Cturdu /	Study Bariatric	N	Baseline	Patients			Patients	with HTN	Post-sur	gery (%)				Resolution
Sludy	Procedure	N	BMI (kg/m²)	with HTN at Baseline (%)	3 mo.	6 mo.	12 mo.	18 mo.	24 mo.	30 mo.	36 mo.	60 mo.	72 mo.	Rate (%)
	LAGB	25	34.4	-	-	-	-	-	-	-	-	-	-	<b>51</b> <sup>e,j</sup>
Raj 2010	LSG	108	34.9	-	-	-	-	-	-	-	-	-	-	<b>32</b> <sup>f,j</sup>
	LRYGB	340	45.3	-	-	-	-	-	-	-	-	-	-	<b>74</b> g,j
Chowbey 2010	LSG	75 <sup>b</sup>	58 [33.3- 77.3] <sup>b</sup>	64	15	9	<b>4</b> c	-	10 <sup>c</sup>	-	-	-	-	86 <sup>h</sup>
Kular 2014b	LMGB	1054	43.2 (7.4)	72	-				5	<b>4</b> <sup>d</sup>				75
Prasad 2012	LSG	110 <sup>a</sup>	44.5 (6.8)	60	-	25	-	-	-	-	-	-	-	86 <sup>i</sup>
Todkar 2010	LSG	23	40.7 (6.6)	43	-	-	-	-	-	-	13	-	-	70



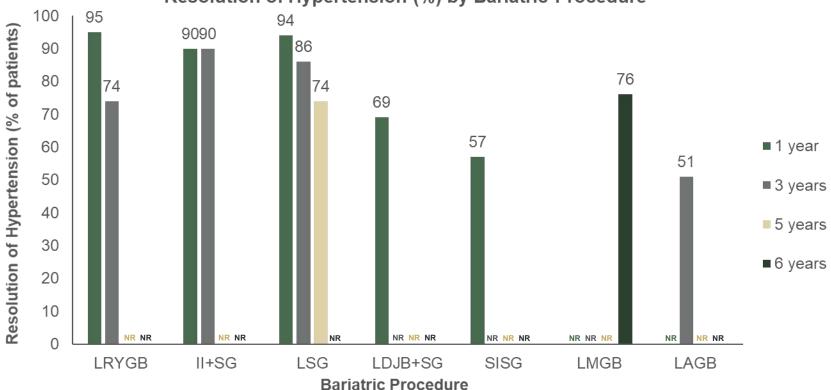
HTN=hypertension. <sup>1</sup>Baseline BMI values are mean (SD) unless otherwise stated. (a) There were 80, 52 and 21 patients followed up at 12, 24 and 36 months; (b) Median [range]; (c) 32 and 7 patients with diabetes mellitus were analyzed after 12 and 24 months of follow-up; (d) Results reported for 6 to 72 months of follow-up; (e) Resolution rate at 38 months post-surgery; (f) Resolution rate at 37 months post-surgery; (g) Resolution rate at 42 months post-surgery; (i) Resolution rate at 24 months post-surgery; (i) Resolution rate at 36 months; (j) The study reported resolution rates but not the percentage of patients with HLD at the respective time points

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## Hypertension: Summary

Resolution of hypertension was commonly defined as normalized blood pressure and cessation of antihypertensive therapy.<sup>1</sup>

The majority of studies reported resolution of hypertension at 1 year post-surgery, with some studies reporting long-term effects up to 6 years following surgery.



**Resolution of Hypertension (%) by Bariatric Procedure** 

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<sup>1</sup>Kota 2012a, Lakdawala 2010, Lakdawala 2011 and Prasad 2010 did not provide a definition for resolution of hypertension J&J India Value Dossier: Bariatric and Metabolic Surgery, 17 December 2015, Data on File NR=Not reported



## **Sleep Apnea**

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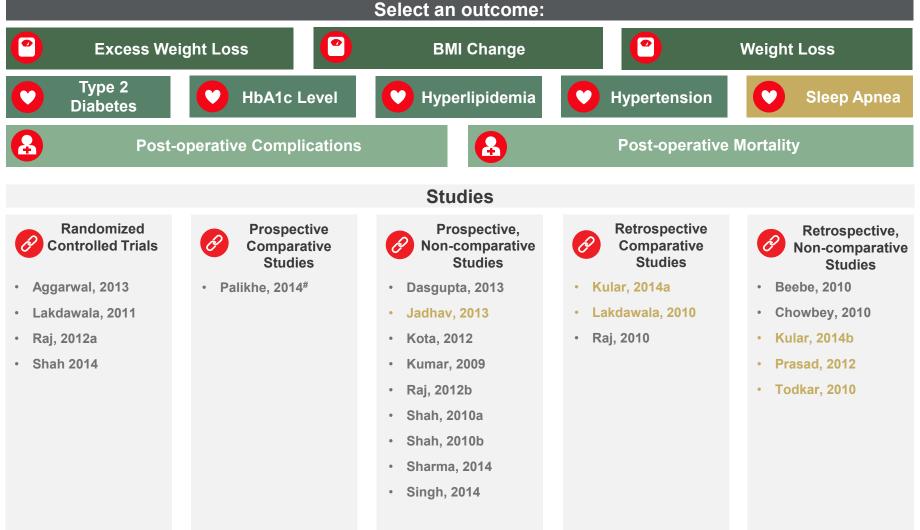
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## Sleep Apnea: Summary



	Bariatric Study Brocodure		Baseline	With Sleep			% of patie		Resolution			
Study	Procedure	N	BMI (kg/m²) <sup>1</sup>	Apnea at Baseline	6 mo	9 mo	12 mo	15 mo	36 mo	60 mo	72 mo	rate (%)
Jadhav 2013 <sup>a</sup>	LSG	42	45 (5)	12	-		0		-	-	-	100
Kular	LSG	118	42 (5.2)	26	-	-	-	-	-	2	-	86
2014a <sup>b</sup>	LMGB	104	44 (3.1)	28	-	-	-	-	-	0.3	-	97
Lakdawala	LRYGB	50	45.2 [33-66] <sup>f</sup>	-	-	-	0	-	-	-	-	100
<b>2010</b> <sup>a</sup>	LSG	50	46.0 [30-85] <sup>f</sup>	-	-	-	0	-	-	-	-	100
Kular 2014b <sup>b</sup>	LMGB	1,054	43.2 (7.4)	32				<b>1</b> g				97
Prasad	LSG	110 <sup>e</sup>	44.5 (6.8)	18	3	-	-	-	-	-	-	85
2012 <sup>c</sup>	200	110	4.0 (0.0)	10	-	-	0	-	-	-	-	100
Todkar 2010 <sup>d</sup>	LSG	23	40.7 (6.6)	22	-	-	-	-	0	-	-	100

There is evidence for the resolution of sleep apnea at both short- and long-term follow-up.

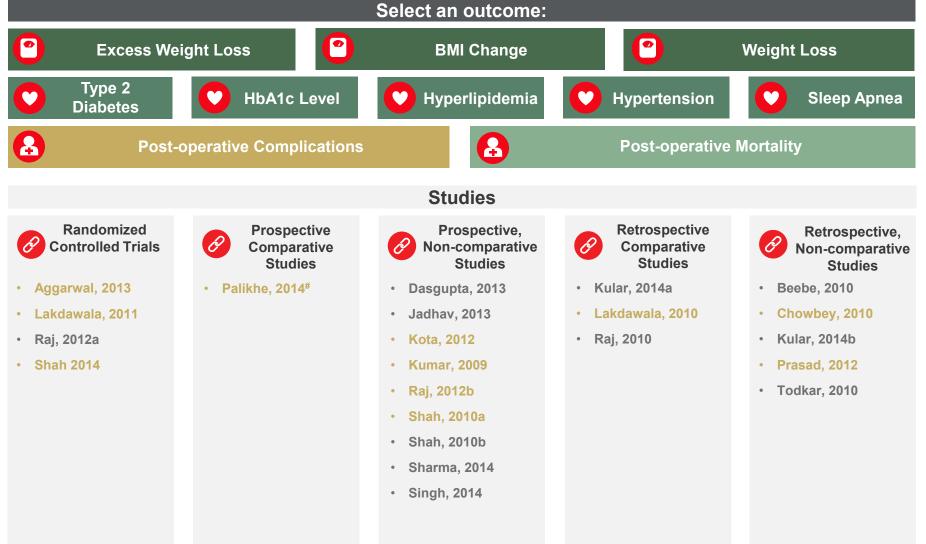
Lakdawala 2010 reported resolution of sleep apnea in all patients within 1 year following LSG and LRYGB.

Kular 2014a reported resolution of sleep apnea in 97% of patients at 5 years follow-up post-LSG and LMGB.

**ETHICON** Shaping the future of SUPGERV PART OF THE Johnson-Johnson FAMILY OF COMPANIES PART OF THE Johnson-Johnson FAMILY OF COMPANIES A state of the distance of the page as a state of the minimum 95% SPO<sub>2</sub> during the night without using a supportive device; (c) Resolution of sleep apnea was defined as having the minimum 95% SPO<sub>2</sub> during the night without using a supportive device; (c) Resolution of sleep apnea was defined as remission of sleep apnea symptoms; (d) Resolution was evidenced by laboratory results within the normal reference values with no medication; (e) There were 52 and 10 patients followed up at 12 and 24 months; (f) There were 80 patients followed up at 12 months; (d) Results reported for 6 to 72 months of follow-up

### **Post-operative Complications**





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## **Post-operative Complications**



Study	Bariatric Procedure	N	Baseline BMI	Complication Rate (%)				
	Danather rocedure	N	(kg/m²) <sup>1</sup>	Major	Minor	Overall		
Aggarwal 2013	LSG (Staple line oversewing)	30	<b>49.8 [37-72]</b> <sup>a</sup>	0	0	0		
	LSG	30	<b>49.3 [35-77]</b> <sup>a</sup>	10	0	10		
Lakdawala 2011	LSG	50	<b>43 [34-59]</b> <sup>a</sup>	0	-	-		
	SISG	50	<b>41 [32-58]</b> <sup>a</sup>	0	-	-		
Shah 2014	LSG (Staple line reinforcement wit PDS-V)	51	46.1 (8.5)	-	-	4		
	LSG	49	44.7 (9.8)	-	-	10		
Palikhe 2014	LSG	14	40.5 (4.6)	14	-	-		
Kota 2012	II+SG	43	33.2 (7.8)	0	-	-		
Kumar 2009	II+SG	30	-	0	0	0		
Raj 2012b	LDJB+SG	38	42.3 (3.5)	0	3	3		
Shah 2010a	LSG	53	45.2 (9.3)	0	0	0		
Lakdawala 2010	LRYGB	50	45. 2 [32-66] <sup>a</sup>	2	2	2		
Lakuawala 2010	LSG	50	<b>46 [30-85]</b> ª	2	2	3		
Chowbey 2010	LSG	75	58.0 [33.3-77.3]ª	0	5	5		
Prasad 2012	LSG	108	44.5 (6.8)	-	-	17		



<sup>1</sup>BMI values are mean (SD) unless otherwise stated (a) Median [range] rv PDS-V=Polydioxanone V-shaped Click to proceed to Concluding Statement

## Post-operative Complications: Summary

Rates of post-operative complications were reported to be between 0% and 17% following bariatric surgery.

### **Major Complications**

- There were 9 studies that reported major complications as a safety outcome.<sup>1</sup>
- Pooled results revealed that major complications occurred in 2% of patients who went through each procedure.<sup>2</sup>
- No cases of major complication were recorded after SISG, II+SG or DJB+SG.

### **Minor Complications**

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- The rates of minor postoperative complications were 0%, 2.0%, 2.0% and 3.0% following II+SG, LRYGB, LSG and LDJB+SG respectively.<sup>3</sup>
- However, the specifics of these events were imprecisely reported; results should therefore be interpreted with caution.

## **Post-operative Mortality**

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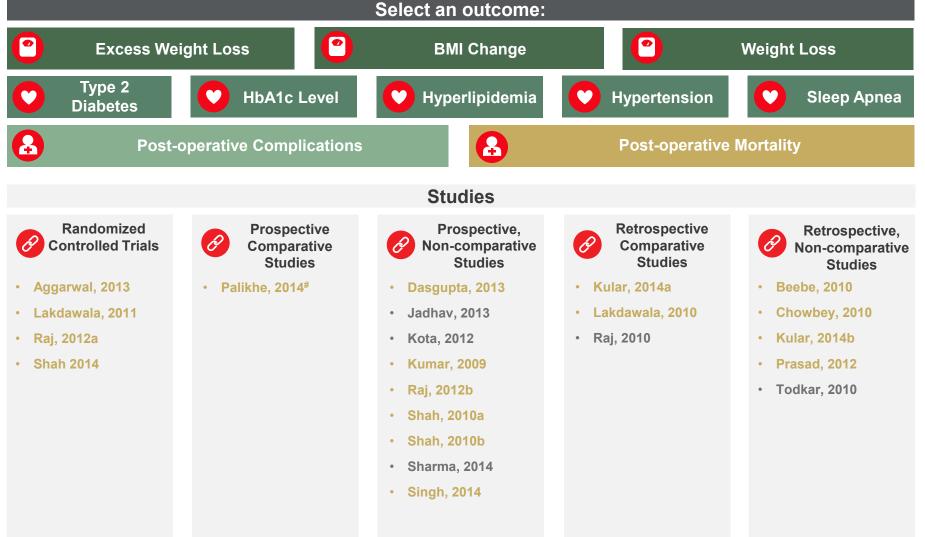
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# Post-operative Mortality: Summary



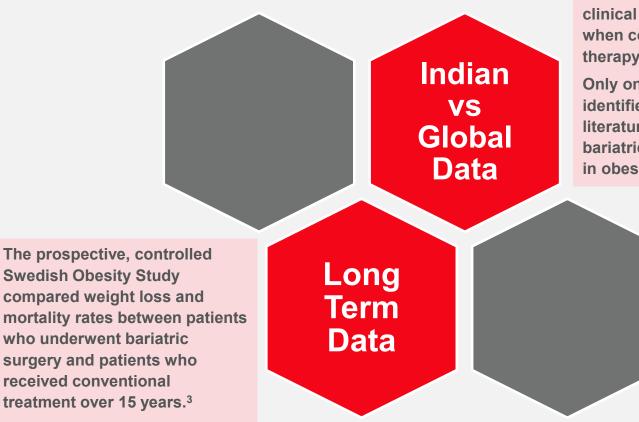
Procedure	Number of Pooled Studies	Total Number of Participants	Number of Deaths	Rate of Mortality
LSG	12	774	3	0.37%
LRYGB	3	419	0	0%
II+SG	1	30	0	0%
LDJB+SG	1	38	0	0%
LMGB	1	1,054	2	0.2%
LAGB	1	25	0	0%
SISG	1	50	0	0%
LAGB/LRYGB/LSG	1	100	1	1%
Overall	-	2,452	6	0.25%

A total of six deaths were reported out of 2,452 patients who underwent bariatric surgery. Thus, the pooled mortality rate associated with bariatric surgery was approximately 0.25%.





Click to view the evidence for bariatric surgery vs standard care in obesity:



Several meta-analyses report the clinical efficacy of bariatric surgery when compared to conventional therapy in the treatment of obesity.<sup>1</sup>

Only one Indian study was identified in the present systematic literature review that compared bariatric surgery with standard care in obesity.<sup>2</sup>

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<sup>1</sup>Gloy 2013, Picot 2009, Ribaric 2014 <sup>2</sup>Palikhe 2014 <sup>3</sup>Sjöström 2007



The prospective, observational Indian study by Palikhe 2014 confirms global data from meta-analyses that suggest bariatric surgery is more effective than conventional therapy in BMI reduction, weight loss and excessive weight loss as well as resolution of Type 2 diabetes mellitus in obesity.

Study	Study Design	Population	Intervention	Comparator	Follow-up Duration	Results^
Palikhe 2014 (*	Prospective, observational study	Adults with BMI ≥ 27.5 kg/m²	LSG	Lifestyle modifications and medical management*	≥ 6 mo	<ul> <li>BMI reduction: -11.3 vs3.3 kg/m<sup>2</sup>; p &lt; 0.05</li> <li>Weight loss: -28 vs. 8.6 kg; p &lt; 0.05</li> <li>EWL: 61.2% vs. 27.4%</li> <li>Resolution of diabetes: 36% vs 0%</li> </ul>
Gloy 2013	RCTs (11 studies)	Adults with BMI ≥ 30 kg/m²	Various bariatric surgery techniques	Diet, medical management, behavioral therapy	≥ 6 mo	<ul> <li>Weight loss:</li> <li>All techniques: WMD = -25.9 kg [-30.9; -21.0]</li> <li>LAGB: WMD = -22.6 kg [-28.4; -16.7]</li> <li>LRYGB: WMD = -28.6 kg [-38.1; -19.1]</li> <li>Reduction in waist circumference:</li> <li>All techniques: WMD = -15.6 cm [-18.1; -13.0]</li> <li>LAGB: WMD = -15.2 cm [-19.2; -11.2]</li> </ul>
Picot 2009	RCTs and non-RCTs (26 studies)	Adults with BMI ≥ 30 kg/m²	Various bariatric surgery techniques	Medical management, usual care or no treatment	≥ 12 mo	<ul> <li>Weight loss:</li> <li>10 years post-surgery: 16% vs 1.5%</li> <li>EWL:</li> <li>1 year post-LAGB: 78.6% vs 41%</li> <li>2 years post-LAGB: 36-87% vs 4-22%</li> </ul>
Ribaric 2014	RCTs and non-RCTs (16 studies)	Adults with mean BMI ≥ 25 kg/m²	Bariatric surgery	Conventional medical therapy	Not Reported	<ul> <li>BMI reduction:</li> <li>WMD post-surgery = -8.28 kg/m<sup>2</sup> [-9.64; -6.92]; p&lt;0.001 when compared to conventional medical therapy</li> <li>EWL: 75.3% vs 11.3%</li> </ul>



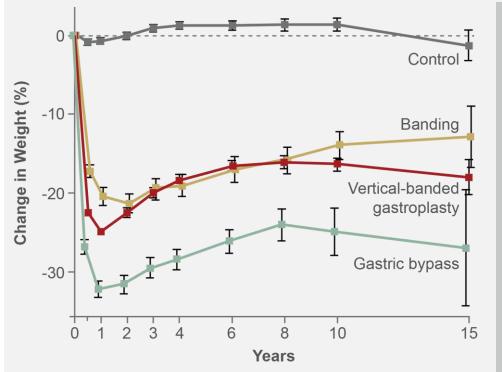
EWL=excess weight loss; WMD=weighted mean difference

\*Medical management was exenatide as anti-diabetic therapy

of surgery ^Unless otherwise stated, results reported are for bariatric surgery vs conventional therapy



The Swedish Obesity Study was a prospective, controlled trial that reported the effects of bariatric surgery on weight change, resolution of comorbidities (diabetes, lipid disturbances, hypertension and hyperuricemia) and mortality amongst 4047 obese subjects (surgery group, n=2010 vs matched control group, n=2037).



Mean percent weight change in the control group and 3 surgical subgroups over a follow-up duration of 15 years. I bars denote 95% confidence intervals.

### Weight Change

Control subjects reported less than  $\pm 2\%$  weight change during the 15 year follow-up period.

Maximum weight loss for subjects who underwent bariatric surgery was 32% following gastric bypass, 25% following vertical-banded gastroplasty and 20% following banding.

After 10 years, percentage weight loss from baseline were stabilized at 25%, 16% and 14% respectively.

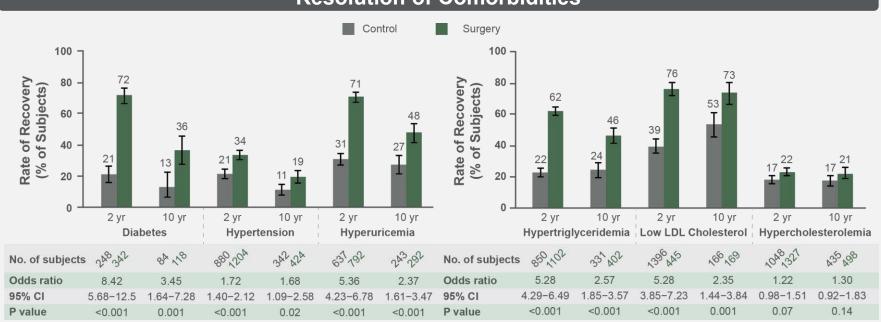
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Sjöström 2007, Sjöström 2008





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**Resolution of Comorbidities** 

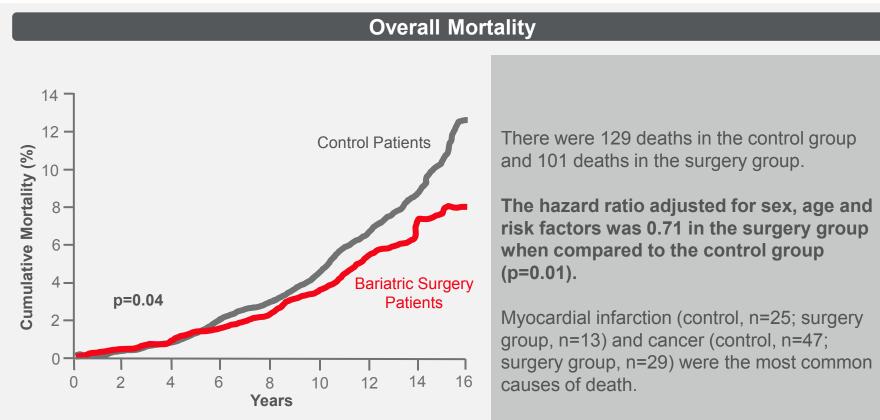
Resolution of diabetes, lipid disturbances, hypertension and hyperuricemia at 2 years and 10 years of follow-up in control and surgery groups.

The surgery group reported higher resolution rates of diabetes, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension and hyperuricemia than the control group. The hypercholesterolemia resolution rate did not differ between the groups.





The Swedish Obesity Study was a prospective, controlled trial that reported the effects of bariatric surgery on weight change, resolution of comorbidities (diabetes, lipid disturbances, hypertension and hyperuricemia) and mortality amongst 4047 obese subjects (surgery group, n=2010 vs matched control group, n=2037).



Unadjusted cumulative mortality in the control and surgical group over a follow-up duration of 16 years.

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## Abstract: Aggarwal 2013



Aggarwal S, Sharma AP, Ramaswamy N. Outcome of laparoscopic sleeve gastrectomy with and without staple line oversewing in morbidly obese patients: a randomized study. *Journal of Laparoscopic and Advanced Surgical Techniques.* 2013; 23(11): 895-899.

#### Introduction

Laparoscopic sleeve gastrectomy (LSG) is a popular bariatric procedure with a low complication rate. Serious complications after LSG include gastric leak and staple line bleeding. In order to reduce these complications, staple line reinforcement has been practiced variably by many surgeons. There is no conclusive evidence to suggest that routine oversewing of the staple line or reinforcement with buttressing material after LSG decreases these complications. We therefore undertook a prospective randomized controlled trial to evaluate the impact of oversewing of the staple line in preventing complications after LSG.

### **Patients and Methods**

Sixty patients undergoing LSG were randomly allocated to two groups. In Group A, the entire staple line was reinforced with continuous suturing, and in Group B, no reinforcement was used. Thirty patients were enrolled in each group. Indications for this procedure were morbidly obese (body mass index  $\geq$ 40 kg/m(2)) or severely obese (body mass index  $\geq$ 35 kg/m(2)) patients with comorbidities including type 2 diabetes mellitus, hypertension, sleep apnea, and osteoarthritis. Complications including gastric leak, bleeding, and stricture were recorded.

#### **Results**

The demographic parameters were comparable in the two groups. Two cases of early gastric leak occurred in Group B and none in Group A. There was no case of staple line bleeding or stricture in either group, although 1 patient in Group B had bleeding from the omentum that required re-operation. The overall surgical complication rate was 5%. The mean operative time in Group A (139 $\pm$ 10 minutes) was significantly greater than in Group B (117 $\pm$ 19 minutes) (P=.02).

### Conclusions

Oversewing of the staple line may lead to reduction in leak rate, although a larger study is required to reach a definitive conclusion. The incidence of staple line bleeding can be minimized by following meticulous technique and adequate compression time after closure of the stapler rather than placing undue emphasis on oversewing and expensive buttressing materials.





### Abstract: Lakdawala 2011



Lakdawala MA, Muda NH, Goel S, Bhasker A. Single-incision sleeve gastrectomy versus conventional laparoscopic sleeve gastrectomy--a randomised pilot study. *Obesity Surgery*. 2011; 21(11): 1664-1670.

#### Background

This is a prospective pilot study done to evaluate the feasibility and to assess the outcomes and complication rates of the singleincision sleeve gastrectomy versus the conventional five-port laparoscopic sleeve gastrectomy.

#### Methods

A prospective comparative analysis was done of 50 patients in each arm who underwent laparoscopic sleeve gastrectomy and singleincision sleeve gastrectomy from September 2009 until April 2010. Both groups were matched for age, gender and BMI and were then randomly assigned to either group. Postoperative pain scoring was done using the visual analogue scale. Postoperative outcomes in terms of pain scores, excess weight loss, resolution of comorbidities and complication rates were compared in both groups, at the end of 6 months.

#### Results

Operating times in both groups were comparable with experience. Intraoperative blood loss was similar in both groups. VAS scoring revealed lesser postoperative pain after the first 8 h in the single-incision group as compared to the laparoscopy group-P < 0.0001. At 6 months, excess weight loss and resolution of comorbidities were comparable in both groups. There were no major complications or mortalities in either group.

### Conclusions

Single-incision laparoscopic sleeve gastrectomy is a feasible surgical procedure for morbid obesity in selected individuals. When compared to conventional laparoscopic sleeve gastrectomy, it has equally effective weight loss and resolution of comorbidities. It also has the added benefits of little or no visible scarring and reduced postoperative pain.



g http://www.ncbi.nlm.nih.gov/pubmed/21789509



## Abstract: Raj 2012a



Raj PP, Kumaravel R, Chandramaliteeswaran C, Rajpandian S, Palanivelu C. Is Laparoscopic Duodenojejunal Bypass with Sleeve an Effective Alternative to Roux En Y Gastric Bypass in Morbidly Obese Patients: Preliminary Results of a Randomized Trial. *Obesity Surgery*. 2012; 22(3): 422-426.

### Background

The incidence of obesity and related metabolic disorders in India and that of stomach carcinoma is one of the highest in the world. Hence, one requires a procedure that allows postoperative surveillance of the stomach with the best outcomes in terms of weight control and resolution of co-morbidities. Here, we compare one such procedure, duodenojejunal bypass with sleeve against the standard Roux-en Y gastric bypass.

### Methods

Fifty-seven patients who were selected for a bypass procedure were randomized into two groups of laparoscopic duodenojejunal bypass with sleeve (DJB) and laparoscopic Roux en Y gastric bypass. The limb lengths were similar in both the groups, and the sleeve was done over a 36F bougie.

### **Results**

The mean body mass index and percent excess weight loss at the end of 3, 6, and 12 months between the groups were not statistically significant. The operating times were higher in the DJB group. The rate of resolution of diabetes, hypertension, and dyslipidemias were also similar with no statistical significance. There was 100% resolution of dyslipidemias in both groups. There was one patient in the DJB group who presented with internal herniation 1 month post-op and was managed surgically. There was no mortality in both the groups.

### Conclusion

Laparoscopic duodenojejunal with sleeve gastrectomy, a procedure which combines the principles and advantages of sleeve gastrectomy and foregut hypothesis, is a safe and effective alternative to gastric bypass in weight reduction and resolution of comorbidities especially for Asian countries. But, long-term follow-up is required.



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### Abstract: Shah 2014



### Shah S, Todkar J, Shah P. Buttressing the staple line: a randomized comparison between staple-line reinforcement versus no reinforcement during sleeve gastrectomy. *Obesity Surgery*. 2014; 24(12): 2014-2020.

Bariatric surgery is recommended for Indian patients with body mass index (BMI) >32.5 kg/m(2) with at least one comorbidity and >37.5 kg/m(2) without a comorbidity. In laparoscopic sleeve gastrectomy, bleeding and leakage from the staple line are common post-operative events. Peri-Strips Dry® with Veritas® (PSD-V) is used in staple-line reinforcement. This was a singleinvestigator, multicenter, randomized study of 100 patients undergoing standard sleeve gastrectomy with a 34 or 36 French bougie. Patients were randomized 1:1 to PSD-V or control groups; no buttress material was used in the control group. The primary objective was to assess complication rates (any staple-line bleed or leak from the intra-operative visit through day 30) associated with sleeve gastrectomy. Surgical time (from first incision to closure of last incision) and the number of clips and/or sutures used to control bleeding were also assessed. Fewer staple-line bleeds were observed in the PSD-V group than the control group (23/51 [45.1 %] vs 39/49 [79.6 %] patients; p=0.0005), and the bleeding was of a lower severity (p=0.0002). No staple-line leaks were observed. Surgical time was shorter in patients who received PSD-V (58.8 vs 72.8 min; p=0.0153), and fewer patients required hemostatic clips and/or sutures (10/51 [19.6 %] vs 33/49 [67.3 %] patients; p<0.0001). Fewer patients in the PSD-V than the control group experienced adverse events (2/51 [3.9 %] vs 5/49 [10.2 %] patients). The use of PSD-V reduced the incidence and severity of staple-line bleeding and was associated with a reduction in surgical time compared with no staple-line reinforcement.



http://www.ncbi.nlm.nih.gov/pubmed/25129485

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### Abstract: Palikhe 2014



Palikhe G, Gupta R, Behera BN, Sachdeva N, Gangadhar P, Bhansali A. Efficacy of laparoscopic sleeve gastrectomy and intensive medical management in obese patients with type 2 diabetes mellitus. *Obesity Surgery*. 2014; 24(4): 529-535.

### Background

There are a dearth of studies comparing laparoscopic sleeve gastrectomy (LSG) and intensive medical treatment (IMT) in obese type 2 diabetes mellitus (T2DM) patients. This study compares these modalities in terms of weight loss, metabolic parameters and quality of life (QOL) score.

#### Methods

We evaluated the efficacy of LSG (n = 14) vs. IMT (n = 17) comprising of low calorie diet, exenatide, metformin and if required insulin detemir in 31 obese T2DM patients with BMI of  $37.9 \pm 5.3$ kg/m(2) and target HbA1c < 7 %. The mean (±SD) age of the patients was  $49.6 \pm 11.9$  years and 74 % were women. The mean duration of diabetes was  $8.5 \pm 6.1$  years and mean HbA1c was  $8.6 \pm 1.3$  %. Primary end point was excess body weight loss (EBWL) at the final follow-up.

### Results

The mean duration of follow-up was  $12.5 \pm 5.0$  (median 12) months. EBWL was  $61.2 \pm 17.6$  % and  $27.4 \pm 23.6$  % in LSG and IMT group respectively (p < 0.001). Glycemic outcomes improved in both with mean HbA1c of  $6.6 \pm 1.5$  % in LSG and  $7.1 \pm 1.2$  % in IMT group. In LSG group, there was resolution of diabetes and hypertension in 36 and 29 % of patients respectively while none in the IMT group. HOMA-IR, hsCRP, ghrelin and leptin decreased while adiponectin increased significantly in LSG compared to IMT group. QOL score improved in LSG as compared to IMT.

### Conclusions

In obese T2DM patients, LSG is superior to IMT in terms of weight loss, resolution of comorbidities and QOL score.



g http://www.ncbi.nlm.nih.gov/pubmed/24272885



# Abstract: Dasgupta 2013



Dasgupta A, Wasir J, Beloyartseva M, Malhotra S, Mithal A. An observational longitudinal study of the impact of sleeve gastrectomy on glycemic control in type 2 diabetes mellitus. *Diabetes Technology and Therapeutics*. 2013; 15(12): 990-995.

#### Background

Laparoscopic sleeve gastrectomy is increasingly being acknowledged as an effective independent bariatric procedure for obese persons with type 2 diabetes. Data on laparoscopic sleeve gastrectomy from India on this group of patients are limited. This study presents 12-month follow-up data of laparoscopic sleeve gastrectomy on obese Indian patients with type 2 diabetes.

#### **Subjects and Methods**

In total, 43 obese patients with type 2 diabetes who received sleeve gastrectomy surgery in the Department of Bariatric Surgery, Medanta the Medicity, Gurgaon, India, were evaluated prospectively for a period of 1 year.

#### Results

Seven patients missed follow-up visits, and one patient died, leaving 35 patients who were analyzed. The mean glycated hemoglobin (HbA1c) levels at baseline and 12 months after surgery were 7.94 $\pm$ 1.9% and 5.80 $\pm$ 0.7%, respectively (P<0.001). Of these, 77.14% reached the primary end point of HbA1c level  $\leq$ 6% without medication. HbA1c level at target (i.e., <7%) occurred in 91.4%. The mean body weight decreased from 122.08 $\pm$ 23.32 kg to 83.43 $\pm$ 15.12 kg at 12 months (P<0.001). The percentage of weight loss and percentage of excess weight loss at 12 months were 31.14 $\pm$ 7.8% and 61.52 $\pm$ 15%, respectively. Antidiabetes medication use decreased from 88.57% to 11.4%.

#### Conclusions

Laparoscopic sleeve surgery is a safe and effective treatment option among the obese Indian type 2 diabetes population with significant remission rates. Follow-up studies are necessary to assess the long-term durability of these results.





## Abstract: Jadhav 2013



Jadhav S and Borude S. Laparoscopic sleeve gastrectomy in remission of obesity and associated co-morbidities. *Medical Journal of Dr. D.Y. Patil University*. 2013; 6(2): 151-154.

#### Background

There is a lot of discussion on bariatric surgery and its effect on weight loss as well as resolution of associated conditions such as diabetes, sleep apnea, and thyroid imbalance. Recent reports also indicate role of laparoscopic sleeve gastrectomy (LSG) in non-obese diabetics.

#### Aims

This study was undertaken to assess medium-term effects of LSG on body weight and co-morbid factors such as diabetes, hypertension, and thyroid imbalance.

#### **Materials and Methods**

A total of 42 obese subjects (19 males and 23 females; age: 23-65 years; body mass index [BMI]:  $45 \pm 5 \text{ kg/m}^{1/4}$ ) underwent evaluation of anthropometric/clinical parameters and blood sugar, hypertension and thyroid function tests before, 3 and 9-15 months after LSG.

#### **Results**

Mean BMI decreased from 45 to 38 after 3 months and 30 at 9-15 months after surgery. Remission of type 2 diabetes mellitus and hypertension occurred in all patients except one. Sleep apnea and asthma was cured in all five patients. Out of the five patients with thyroid imbalance, all except one were off medication within 5 months.

#### Conclusion

Our study showed that LSG is effective in producing a significant and sustained weight loss and improving diabetes mellitus, hypertension, and other co-morbid factors in obese patients.





http://www.mjdrdypu.org/article.asp?issn=0975-2870;year=2013;volume=6;issue=2;spage=151;epage=154;aulast=Jadhav

## Abstract: Kota 2012



Kota SK, Ugale S, Gupta N, Naik V, Kumar KV, Modi KD. Ileal interposition with sleeve gastrectomy for treatment of type 2 diabetes mellitus. *Indian Journal of Endocrinology and Metabolism*. 2012; 16(4): 589-598.

#### Aim

Combination of laparoscopic ileal interposition (II) with sleeve gastrectomy (SG) is an upcoming procedure, which offers good metabolic improvement and weight reduction without causing significant malabsorption. The objective of this study was to evaluate the results of this novel procedure for control of type 2 diabetes, obesity, hypertension, and related metabolic abnormalities.

#### **Materials and Methods**

The II and SG was performed in 43 patients (M:F = 25:18) from February 2008. Participants had a mean age of  $47.2 \pm 8.2$  years (range 29-66 years), mean duration of diabetes of  $10.1 \pm 9.2$  years (range 1-32 years), and mean preoperative body mass index (BMI) of 33.2  $\pm 7.8$  kg/m2. All patients had poorly controlled type 2 diabetes mellitus (DM) [mean glycated hemoglobin (HbA1C) 9.6  $\pm 2.1\%$ ] despite use of oral hypoglycemic agents (OHAs) and/or insulin. Thirty (70%) patients had hypertension, 20 (46%) had dyslipidemia, and 18 (42%) had significant microalbuminuria. The primary outcome was remission of diabetes (HbA1C < 6.5% without OHAs/insulin) and the secondary outcomes were reduction in antidiabetic agent requirement and components of metabolic syndrome.

#### **Results**

Mean follow-up was for  $20.2 \pm 8.6$  months (range 4-40 months). Postoperatively, glycemic parameters (fasting and post-lunch blood sugar, HbA1C improved in all patients (P < 0.05) at all intervals. Twenty (47%) patients had remission in diabetes and the remaining patients showed significantly decreased OHA requirement. All patients had weight loss between 15 and 30% (P < 0.05). Twenty-seven (90%) patients had remission in hypertension. At 3 years, the mean fall in HbA1C (34%) was more than reduction in BMI (25%). There was a declining trend in lipids and microalbuminuria postoperatively, though it was significant for microalbuminuria only.

#### Conclusions

The laparoscopic II with SG seems to be a promising procedure for control of type 2 DM, hypertension, weight reduction, and associated metabolic abnormalities. A multicenter study with larger number of patients and a longer follow-up period is needed to substantiate our preliminary findings.





## Abstract: Kumar 2009



Kumar KV, Ugale S, Gupta N, Naik V, Kumar P, Bhaskar P, Modi KD. Ileal interposition with sleeve gastrectomy for control of type 2 diabetes. *Diabetes Technology and Therapeutics*. 2009; 11(12): 785-789.

#### Background

Bariatric surgery offers the best solution in management of obesity and related metabolic ailments, paving the way for a concept termed metabolic surgery. We report the results of a novel surgical procedure on glycemic control and metabolic syndrome in poorly controlled type 2 diabetes.

### Methods

Ten patients (four men, six women) underwent laparoscopic surgical procedure of sleeve gastrectomy and ileal interposition. All patients had diabetes for more than 3 years with poor control despite use of oral hypoglycemic agents (OHAs) and/or insulin. The primary outcome was remission of diabetes (hemoglobin A1c <7% without OHAs/insulin), and secondary outcomes were change in OHA requirement, components of metabolic syndrome, insulin resistance, and microalbuminuria.

### **Results**

We report the preliminary postoperative follow-up data of 9.1 +/- 5.3 months (range, 2-16 months). Participants had a mean age of 48.2 +/- 9 years (range, 34-62 years), duration of diabetes of 11 +/- 5.7 years (range, 4-25 years), and preoperative body mass index of 33.8 +/- 6.5 kg/m(2). Seven patients had diabetes remission, and the remaining three showed significantly decreased OHA requirement. All participants had weight loss ranging between 15% and 30% and had remission of hypertension. Microalbuminuria (96.8 +/- 19.1 vs. 46.7 +/- 10.1 mg/L, P = 0.03568) and insulin resistance as assessed by homeostasis assessment model of insulin resistance (5.2 +/- 2.1 vs. 1.8 +/- 0.9, P = 0.0005) decreased significantly after surgery.

## Conclusions

Our preliminary observations demonstrated the feasibility, safety, and efficacy of this novel surgical procedure in type 2 diabetes. Further long-term data from more patients are necessary to confirm these findings.





# Abstract: Raj 2012b



Raj PP, Kumaravel R, Chandramaliteeswaran C, Vaithiswaran V, Palanivelu C. Laparoscopic duodenojejunal bypass with sleeve gastrectomy: preliminary results of a prospective series from India. *Surgical Endoscopy*. 2012; 26(3): 688-692.

## Background

Bariatric surgeries are now redefined as metabolic surgeries given the excellent resolution of metabolic derangements accompanying obesity. Duodenojejunal bypass (DJB) is a novel metabolic surgery based on foregut hypothesis. Reports describe DJB as a stand-alone procedure for the treatment of diabetes in nonobese subjects. For obese subjects, DJB is combined with sleeve gastrectomy. This combination of DJB and sleeve gastrectomy is proposed as an ideal alternative to Roux-en-Y gastric bypass (RYGB) with these advantages: (1) easy postoperative endoscopic surveillance, (2) preservation of the pyloric mechanism, which prevents dumping syndrome, and (3) reduced alimentary limb tension. This study aimed to analyze the short-term outcomes of laparoscopic DJB with sleeve gastrectomy for morbidly obese patients.

## Methods

At our institution, 38 patients who underwent laparoscopic DJB with sleeve gastrectomy were followed up. The inclusion criteria for the study were according to the Asian Pacific Bariatric Surgery Society guidelines. Sleeve gastrectomy was performed over a 36-Fr bougie, with the first part of the duodenum mobilized and transected. The jejunum was divided 50 cm distal to duodenojejunal flexure. A 75- to 150-cm alimentary limb was fashioned and brought in a retrocolic manner. End-to-end hand-sewn duodenojejunostomy was performed. Intestinal continuity was restored with a stapled jejunojejunostomy, and mesenteric rents were closed.

## Results

The study population consisted of 38 patients (15 men and 23 women) ranging in age from 31 to 48 years. During a mean followup period of 17 months, the excess body weight loss was 72%, with a 92% resolution of diabetes. One patient presented with internal herniation through the retrocolic window 1 month after the operation and was managed surgically without any complication. No other minor or major complications occurred, and there was no mortality.

## Conclusion

Laparoscopic DJB with sleeve gastrectomy is safe and effective in achieving durable weight loss and excellent resolution of comorbidities. Long-term follow-up studies are needed.

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## Abstract: Shah 2010a



Shah PS, Todkar JS, Shah SS. Effectiveness of laparoscopic sleeve gastrectomy on glycemic control in obese Indians with type 2 diabetes mellitus. *Surgery for Obesity and Related Diseases*. 2010; 6(2): 138-141.

#### Background

To prospectively evaluate the efficacy and safety of laparoscopic sleeve gastrectomy (LSG) in Indian subjects with type 2 diabetes mellitus and a body mass index >33 kg/m(2) in a tertiary care hospital in Pune, India. Morbid obesity associated with type 2 diabetes mellitus has many health implications. A definitive long-term strategy is needed to control obesity and its deleterious effects. LSG is one such approach.

## Methods

The patients who underwent LSG were followed up until the end of 1 year after surgery. The change in hemoglobin A1c levels, waist circumference, total body weight, and the use of oral hypoglycemic agents and insulin were studied.

## Results

A total of 53 patients (24 men and 29 women, age 46.5 +/- 8.7 years, body mass index 45.2 +/- 9.3 kg/m(2), waist circumference 117 +/- 18 cm, and hemoglobin A1c 8.4% +/- 1.6%) fulfilled the entry criteria and underwent LSG. Before LSG, 48 patients (79%) required antidiabetic medication (oral hypoglycemic agents and insulin) and 5 managed their diabetes with diet control. At 1 month after LSG, 39 (81.2%) of 48 patients no longer required antidiabetic medications and had achieved euglycemia with diet control alone. The use of antidiabetic medications was reduced in 9 (18.8%) of 52 patients. At 1 year, euglycemia was observed in 51 patients (96.2%) without medication and 2 (3.8%) of the 53 patients had reduced their medication dosage.

## Conclusion

LSG is an effective adjunct in the treatment of type 2 diabetes mellitus in obese individuals. It appears that improvement in glycemic control is achieved even before weight reduction, and the possible mechanisms explaining this need further investigation.





## Abstract: Shah 2010b



Shah SS, Todkar JS, Shah PS, Cummings DE. Diabetes remission and reduced cardiovascular risk after gastric bypass in Asian Indians with body mass index <35 kg/m(2). *Surgery for Obesity and Related Diseases*. 2010; 6(4): 332-338.

#### Background

Roux-en-Y gastric bypass (RYGB) benefits patients with type 2 diabetes mellitus (T2DM) and a body mass index (BMI) >35 kg/m(2); however, its effectiveness in patients with T2DM and a BMI <35 kg/m(2) is unclear. Asian Indians have a high risk of T2DM and cardiovascular disease at relatively low BMI levels. We examined the safety and efficacy of RYGB in Asian Indian patients with T2DM and a BMI of 22-35 kg/m(2) in a tertiary care medical center.

## Methods

A total of 15 consecutive patients with T2DM and a BMI of 22-35 kg/m(2) underwent RYGB. The data were prospectively collected before surgery and at 1, 3, 6, and 9 months postoperatively.

## Results

Of the 15 patients, 8 were men and 7 were women (age 45.6 +/- 12 years). Their preoperative characteristics were BMI 28.9 +/- 4.0 kg/m(2), body weight 78.7 +/- 12.5 kg, waist circumference 100.2 +/- 6.8 cm, and duration of T2DM 8.7 +/- 5.3 years. At baseline, 80% of subjects required insulin, and 20% controlled their T2DM with oral hypoglycemic medication. The BMI decreased postoperatively by 20%, from 28.9 +/- 4.0 kg/m(2) to 23.0 +/- 3.6 kg/m(2) (P <.001). All antidiabetic medications were discontinued by 1 month after surgery in 80% of the subjects. At 3 months and thereafter, 100% were euglycemic and no longer required diabetes medication. The fasting blood glucose level decreased from 233 +/- 87 mg/dL to 89 +/- 12 mg/dL (P <.001), and the hemoglobin A1c decreased from 10.1% +/- 2.0% to 6.1% +/- 0.6% (P <.001). Their waist circumference, presence of dyslipidemia, and hypertension improved significantly. The predicted 10-year cardiovascular disease risk (calculated using the United Kingdom Prospective Diabetes Study equations) decreased substantially for fatal and nonfatal coronary heart disease and stroke. No mortality, major surgical morbidity, or excessive weight loss occurred.

## Conclusion

RYGB safely and effectively eliminated T2DM in Asian Indians with a BMI <35 kg/m(2). Larger, longer term studies are needed to confirm this benefit.





## Abstract: Sharma 2014



Sharma A, Aggarwal S, Ahuja V, Bal C. Evaluation of gastroesophageal reflux before and after sleeve gastrectomy using symptom scoring, scintigraphy, and endoscopy. *Surgery for Obesity and Related Diseases*. 2014; 10(4): 600-605.

#### Background

The effect of laparoscopic sleeve gastrectomy (SG) on gastroesophageal reflux disease (GERD) has been a controversial issue. There have been limited studies on this aspect and most of the published studies are retrospective. Therefore, a prospective study was designed to objectively assess the problem. The objective of this study was to assess the impact of SG on symptoms of gastroesophageal reflux using questionnaire, endoscopy, and radionuclide scintigraphy.

#### Methods

Thirty-two patients undergoing laparoscopic sleeve gastrectomy were assessed for gastroesophageal reflux using Carlsson Dent Questionnaire and GERD questionnaire before and after surgery at three monthly intervals. They were also subjected to upper GI endoscopy (UGIE) and radionuclide scintigraphy both pre- and postoperatively.

#### Results

Mean preoperative weight and body mass index were 126.5 kg and 47.8 kg/m2, respectively. Mean percent excess weight loss at 12 months was  $64.3 \pm 18.4$ . Both the Carlsson Dent Score (CDS) and Severity Score (SS) exhibited a decline from 2.88 to 1.63 (p<0.05) and 2.28 to 1.06 (p<0.05), respectively after 12 months. Radionuclide scintigraphy revealed a significant rise of GERD from 6.25% to 78.1% in the postoperative period (p<0.001). UGIE showed a rise in incidence of esophagitis from 18.8% to 25%; however, there was improvement in all patients except one in terms of reduction of severity of esophagitis.

#### Conclusion

Presence of GERD may not be considered as a contra-indication for sleeve gastrectomy. There is improvement of GERD as assessed by symptom questionnaires, as well as improvement in grade of esophagitis. The new onset GERD detected on scintigraphy may not be pathologic as there is a decrease in total acid production postsurgery; however, it still remains an important issue and needs long-term follow-up.





# Abstract: Singh 2014



Singh JP, Tantia O, Chaudhuri T, Khanna S, Patil PH. Is resected stomach volume related to weight loss after laparoscopic sleeve gastrectomy? *Obesity Surgery*. 2014; 24(10): 1656-1661.

#### Background

Laparoscopic sleeve gastrectomy (LSG) was initially performed as the first stage of biliopancreatic diversion with duodenal switch for the treatment of super-obese or high-risk obese patients but is now most commonly performed as a standalone operation. The aim of this prospective study was to investigate outcomes after LSG according to resected stomach volume.

#### Methods

Between May 2011 and April 2013, LSG was performed in 102 consecutive patients undergoing bariatric surgery. Two patients were excluded, and data from the remaining 100 patients were analyzed in this study. Patients were divided into three groups according to the following resected stomach volume: 700-1,200 mL (group A, n = 21), 1,200-1,700 mL (group B, n = 62), and >1,700 mL (group C, n = 17). Mean values were compared among the groups by analysis of variance.

#### Results

The mean percentage excess body weight loss (%EBWL) at 3, 6, 12, and 24 months after surgery was  $37.68 \pm 10.97$ ,  $50.97 \pm 13.59$ ,  $62.35 \pm 11.31$ , and  $67.59 \pm 9.02$  %, respectively. There were no significant differences in mean %EBWL among the three groups. Resected stomach volume was greater in patients with higher preoperative body mass index and was positively associated with resected stomach weight.

#### Conclusions

Mean %EBWL after LSG was not significantly different among three groups of patients divided according to resected stomach volume. Resected stomach volume was significantly greater in patients with higher preoperative body mass index.



g http://www.ncbi.nlm.nih.gov/pubmed/24827404

## Abstract: Kular 2014a



Kular KS, Manchanda N, Rutledge R. Analysis of the five-year outcomes of sleeve gastrectomy and mini gastric bypass: a report from the Indian sub-continent. *Obesity Surgery*. 2014; 24(10): 1724-1728.

#### Background

Few reports have compared laparoscopic sleeve gastrectomy (LSG) to laparoscopic Roux-en-Y procedure (LRNY). This study aims at comparing the 5-year follow-up results of mini gastric bypass (MGB or omega gastric bypass (OGB)) and LSG in terms of weight loss, weight regain, complications, and resolution of co-morbidities.

#### Methods

A retrospective analysis of the prospectively collected database was done from the start of our bariatric practice from February 2007 to August 2008 (minimum 5-year follow-up). During this period, 118 patients underwent LSG. These patients were matched in age, gender, preoperative weight, and BMI to 104 patients who underwent MGB in the same time period. The results were compared.

#### Results

Follow-up was achieved in 72 MGB vs 76 LSG patients up to 5 years. The mean BMI for the MGB and LSG group was  $44 \pm 3.1$  and  $42 \pm 5.2$  kg/m(2), respectively (P < 0.001). The average percentage of excess weight loss (%EWL) for MGB vs LSG was 63 vs 69 % at 1 year and 68 vs 51.2 % at 5 years (P = 0.166), respectively. Post-op gastro-esophageal reflux disease (GERD) was seen in 2.8 % MGB patients and marginal ulcer was diagnosed in 1 MGB patient (1.4 %). GERD was seen in 21 % post-LSG patients.

#### Conclusions

Both MGB and LSG are safe, short, and simple operations. Weight loss is similar in MGB and LSG in the first years, but lesser %EWL with LSG at 5 years (68 % in MGB vs 51 % in LSG). Post-op GERD is more common after LSG.



g http://www.ncbi.nlm.nih.gov/pubmed/24805912

# Abstract: Lakdawala 2010



Click to go back to

evidence summary home

page

Lakdawala MA, Bhasker A, Mulchandani D, Goel S, Jain S. Comparison between the results of laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass in the Indian population: a retrospective 1 year study. *Obesity Surgery*. 2010; 20(1): 1-6.

### Background

Laparoscopic sleeve gastrectomy (LSG) is gaining popularity as a procedure for the treatment of morbid obesity. Its indications and long-term results are currently under evaluation. Initially started as a first-stage procedure for superobese patients, it is now emerging as a standalone procedure in Asia and other parts of the world. Early results suggest that, at the end of 1 year, weight loss and resolution of comorbidities with LSG is comparable to laparoscopic Roux-en-Y gastric bypass (LRYGB). Whether LSG alone can replace LRYGB as a standard bariatric procedure is questionable. The aim of this study is to compare the results, resolution of comorbidities, and complications between LSG and LRYGB.

### Methods

A retrospective comparative analysis was done of 50 patients in each arm who underwent LSG and LRYGB from October 2007 to March 2008. Both groups were matched for age, sex, and body mass index. The resolution of comorbidities, percentage of excess weight loss (EWL), and complications were studied at 6 months and 1 year in our study.

## Results

It was seen that resolution of most comorbidities such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea, joint pains, and percentage of EWL in both groups was comparable at the end of 6 months and 1 year. Though early resolution of type 2 diabetes was seen to be better in the LRYGB group, the results matched up at 1 year. There was increased incidence of gastroesophageal reflux disease in LSG patients. On comparison, it was also observed that the Asian studies have shown better results with LSG when compared to studies done in a largely Caucasian population.

## Conclusions

Long-term studies are needed to evaluate the efficacy of LSG alone as a procedure for the treatment of morbid obesity and its comorbidities.



# Abstract: Raj 2010



Raj PP, Chandramaliteeswaran C, Senthilnathan P, Asokan S, Palanivelu C. Bariatric to metabolic surgery: management options and experience at a tertiary centre. *Journal of the Indian Medical Association*. 2010; 108(10): 645-647.

Obesity proves to be a growing pandemic with severe health and economic implications. Bariatric surgeries are now recognised as metabolic surgeries given the excellent resolution of metabolic derangements accompanying obesity. This concept of metabolic surgery is now applied to non-obese population with metabolic disorders. The type II diabetes mellitus remission rates as high as 95% have been reported, least with restrictive procedures and maximum with malabsorptive procedures and such effect occurs even before substantial weight loss. This has led to increased understanding of diabetes pathophysiology and formulation of foregut and hindgut hypothesis. The aim of this study was to briefly review the management options for morbid obesity and present the results at a high volume centre. Data from 518 patients who underwent laparoscopic bariatric surgeries at this institute since 2002 were taken up for analysis retrospectively. Study population included 518 patients with 310 males and 208 females. Excess body weight loss and comorbidity resolution rates were analysed. Laparoscopic bariatric surgery is safe and effective for excess body weight loss and confers excellent resolution of associated comorbidities.



http://www.ncbi.nlm.nih.gov/pubmed/21510546

## Abstract: Beebe 2010



Beebe D, Goel S, Lakdawala M, Olejniczak M, Jochman J, Singh H, et al. Surgery for Obesity: India versus USA - A Snapshot Perioperative Care Comparison at Two Centers. *Journal of Anaesthesiology Clinical Pharmacology*. 2010; 26(2): 157-161.

#### Background

Surgery to treat obesity is becoming more accepted globally. The surgical expertise available in India is helpful to Indian citizens and patient visitors to India because of cost competitiveness. This report provides perioperative outcomes including cost of bariatric surgery in India versus U.S.A.

#### **Patients and Methods**

During 2006, 200 consecutive bariatric patients in Mumbai and Minneapolis were studied. All received general Anaesthesia for their procedures. Their preoperative morbidity, intraoperative care, early postoperative outcome and costs were compared.

### Results

The BMI was similar (India  $48.3 \pm 7.8$ ; U.S.A.  $48.3 \pm 8.5$ ). In the U.S.A. more patients were hypertensive (53 vs. 37 p =0.033) and likely to be female (80% vs. 60% p =0.032). Multiple co-morbidities were more likely in men in both countries. Laparoscopic roux-en-y gastric bypass (LRYGB) was the more common procedure in U.S.A. (85 vs. 69 p =0.012) with a higher trend to perform the laparoscopic adjustable gastric banding (LAGB) in India with a significantly higher likelihood of the LAGB needing revision (0 vs. 7 p =0.014). The LAGB took half the time in India ( $42.8 \pm 18$  vs.  $80.5 \pm 20$  mins p =0.0001) with the majority being cared for with a proseal LMA (14 vs. 0 p =0.0002). All were intubated for LRYGB with the majority done using a rapid sequence technique in the U.S.A. (45 vs. 0 p =0.0001). Patients with an anticipated difficult airway were handled differently in India vs. U.S.A. The procedure was four times more costly in the U.S.A. (\$32000 vs. \$8000).





# Abstract: Chowbey 2010



Chowbey PK, Dhawan K, Khullar R, Sharma A, Soni V, Baijal M, Mittal T. Laparoscopic sleeve gastrectomy: an Indian experience-surgical technique and early results. *Obesity Surgery*. 2010; 20(10): 1340-1347.

#### Background

Obesity has been observed to be on the rise in the Indian subcontinent. We report our early experience with the laparoscopic sleeve gastrectomy (LSG) for treating morbid obesity in the Indian population along with description of the surgical technique.

## Methods

The data of 75 patients who underwent LSG for the treatment of morbid obesity at the Minimal Access, Metabolic and Bariatric Surgery Centre, Sir Ganga Ram Hospital, Delhi, from November 2006 to February 2009, were retrospectively reviewed from prospective database. The gastric sleeve is created laparoscopically using sequential firings of a linear stapling device applied alongside a 36-Fr calibrating bougie. The data collected included age, gender, initial body mass index (BMI) and excess weight, the co-morbidity status, and preoperative investigations. Perioperative parameters and follow-up details [weight, BMI, excess weight loss (%EWL), resolution of co-morbidities, and postoperative investigations] were noted.

## Results

All procedures were completed laparoscopically. There was no major procedure-related morbidity. Hemorrhage requiring blood transfusion was observed in four patients. One patient died at 2 weeks postoperatively due to pulmonary embolism. There was a steady rise in %EWL from 31.2% at 3 months to 52.3% at 6 months, 59.13% at 1 year, and 65% at 2 years. Type II diabetes was resolved in 81.2%, hypertension in 93.75%, and dyslipidemia in 85% at 1 year.

## Conclusion

Although long-term results are necessary to determine the benefits of the procedure, early results indicate that LSG may be a safe and feasible option for treating the morbidly obese patients.





## Abstract: Kular 2014b



Kular KS, Manchanda N, Rutledge R. A 6-year experience with 1,054 mini-gastric bypasses-first study from Indian subcontinent. *Obesity Surgery*. 2014; 24(9): 1430-1435.

#### Background

We started laparoscopic mini-gastric bypass (MGB) for the first time in India in February 2007 for its reported safety, efficacy, and easy reversibility.

#### Methods

A retrospective review of prospectively maintained data of all 1,054 consecutive patients (342 men and 712 women) who underwent MGB at our institute from February 2007 to January 2013 was done.

### Results

Mean age was 38.4 years, preoperative mean weight was 128.5 kg, mean BMI was 43.2 kg/m(2), mean operating time was  $52 \pm 18.5$  min, and mean hospital stay was  $2.5 \pm 1.3$  days. There were 49 (4.6%) early minor complications, 14 (1.3%) major complications, and 2 leaks (0.2%). In late complications, one patient had low albumin and one had excess weight loss; MGB was easily reversed in both (0.2%). Marginal ulcers were noted in five patients (0.6%) during follow-up for symptomatic dyspepsia, and anemia was the most frequent late complication occurring in 68 patients (7.6%). Patient satisfaction was high, and mean excess weight loss was 84, 91, 88, 86, 87, and 85% at years 1 to 6, respectively.

#### Conclusion

This study confirms previous publications showing that MGB is quite safe, with a short hospital stay and low risk of complications. It results in effective and sustained weight loss with high resolution of comorbidities and complications that are easily managed.





## Abstract: Prasad 2012



Prasad P, Tantia O, Patle N, Khanna S, Sen B. An analysis of 1-3-year follow-up results of laparoscopic sleeve gastrectomy: an Indian perspective. *Obesity Surgery*. 2012; 22(3): 507-514.

#### Background

Laparoscopic sleeve gastrectomy (LSG) has become very popular nowadays among bariatric surgeons because of its surgical simplicity and good postoperative results. We present our experience on LSG as a single stage primary bariatric procedure for morbid obesity and its 1-3-year follow-up results.

#### Methods

Between March 2008 and March 2011, a total of 110 patients underwent laparoscopic sleeve gastrectomy. Two patients were excluded from the study and thus the prospectively maintained data of 108 patients were retrospectively reviewed and outcomes were recorded.

#### Results

The mean patient age was  $39.3 \pm 11.1$  years, mean body mass index was  $44.5 \pm 6.8$ , mean excess body weight was  $54.1 \pm 16.3$  kg, and the mean American Society of Anesthesiologists score was  $3.1 \pm 0.57$ . The mean operative time for the LSG procedure was  $64.8 \pm 10.6$  min. The minimum follow-up duration was 6 months and maximum of 36 months. The mean postoperative percent excess body weight loss achieved was  $67.5 \pm 13.0$  at 1 year,  $71.1 \pm 13.8$  at 2 years, and  $66.09 \pm 14.3$  at 3 years. At the end of 3 years, there was 83.3% resolution in diabetes, 85.7% resolution in hypertension, and 85.71% resolution in dyslipidemia. There were no reports of postoperative hemorrhage, gastric leak, deep venous thrombosis, pulmonary embolism, delayed gastric tube stricture, and operative mortality.

#### Conclusions

LSG is a safe and effective bariatric procedure with low perioperative complications. Before it is considered as a single stage primary procedure, a long-term prospective comparative study with other bariatric procedures is required.





## Abstract: Todkar 2010



Todkar JS, Shah SS, Shah PS, Gangwani J. Long-term effects of laparoscopic sleeve gastrectomy in morbidly obese subjects with type 2 diabetes mellitus. *Surgery for Obesity and Related Diseases*. 2010; 6(2): 142-145.

## Background

Laparoscopic sleeve gastrectomy (LSG) is becoming popular as a stand-alone procedure for the treatment of morbid obesity and related diseases. This retrospective study presents the outcomes of LSG with regard to weight loss and improvement in co-morbidities and quality of life (QOL) at the end of 3 years after surgery in a tertiary care hospital in Pune, India.

## Methods

A total of 23 patients with type 2 diabetes mellitus (6 men and 17 women) with morbid obesity (mean body mass index 40.7 +/-6.6 kg/m(2)) who had undergone LSG from 2004 to 2005 were selected for the present analysis. The percentage of excess weight loss and changes in co-morbidity status and QOL at the end of 3 years were calculated. The patients were simultaneously evaluated using the Bariatric Analysis and Reporting Outcome System scores. P values <.05 were considered significant.

## Results

At 36 months after surgery, the percentage of excess weight loss was 74.58%, a significant number of patients (16 of 23, P <.05) had had improvement in all co-morbidities, and 7 showed improvement in >or=1 co-morbidity. All patients indicated improvement in their QOL but not equally for all parameters included in the questionnaire. The Bariatric Analysis and Reporting Outcome System score was good in 4, very good in 4, and excellent in 15 of the 23 patients.

## Conclusion

Our data have shown that LSG is a highly effective and safe procedure for achieving weight loss, improving co-morbidities, and improving the QOL in patients with type 2 diabetes mellitus and morbid obesity during a long-term period.



