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1 Early Effects of Bougie Size on Sleeve Gastrectomy Outcome

2 Abstract

3 Background:

4 When performing sleeve gastrectomy (SG) a bougie (32-60 fr.) is used. We
5 evaluated two different bougie sizes on early post-operative outcomes and long-term
6 weight loss.

7 Materials & Methods:

8 A one-year prospective study was conducted on patients undergoing SG. In the
9 first 6 months patients had 32-fr. bougie (Group-1); in the second 6 months they had 36-
10 fr. bougies (Group-2).

11 Results:

12 We evaluated 131 patients. No intra-operative complications or mortality
13 occurred. Post-operatively, Group-1 (n=72) had a longer hospital stay (1.6 ± 0.8 vs.
14 1.3 ± 0.5 days $p=0.04$) and used more Ondansetron for nausea than Group-2 (n=59)
15 (6.7 ± 8.0 vs. 5.3 ± 4.5 mg $p=0.2$ respectively). Ten (14%) patients in Group-1 returned to
16 the emergency department compared to five (9%) in Group-2. One-year percent excess
17 weight loss was similar ($73.0\pm 20.6\%$ vs. $71.1\pm 20.9\%$, $p=0.73$ respectively).

18

19 Conclusion:

20 The smaller bougie resulted in a longer hospital stay, with tendency toward
21 increased nausea, more emergency department visits and readmissions. Long-term weight
22 loss was not affected.

23

24 **Key Words:** Sleeve Gastrectomy, Bougie, Complications, Length of stay, ED visits

1

2

ARTICLE

3 INTRODUCTION:

4 Morbid obesity has become increasingly prevalent in the United States and in other
5 countries. Recent analysis shows that approximately six percent of adults in the United States
6 are morbidly obese ⁽¹⁾. Because medical management has demonstrated variable success, other
7 methods have emerged offering surgical options as alternatives for weight loss with promising
8 outcomes. Sleeve gastrectomy (SG) was originally constructed as the initial stage of bilio-
9 pancreatic diversion with duodenal switch (BPD/DS). Today, SG used as a stand-alone
10 operation, is becoming an effective primary weight-loss procedure showing weight loss close to
11 Roux-en-Y Gastric Bypass and BPD/DS⁽²⁾. Consensus on surgical technique, in particular bougie
12 size used during sleeve construction, has yet to be uniformly established. Parikh et al showed
13 that SG resulted in substantial percent excess weight loss (%EWL), near 50% at one year, with
14 no significant correlation with bougie size ⁽³⁾. Our goal was to evaluate the early effects of
15 bougie size on patient outcomes, primarily hospital length of stay (LOS), nausea, 30-day
16 morbidity and mortality including Emergency Department (ED) returns and hospital re-
17 admissions, and %EWL, using two different bougie sizes: 32 and 36 French (fr.).

18

19 MATERIALS & METTHODS:

20 We conducted a prospective study on all patients who were candidates to undergo elective SG in
21 one year. Intra-operative and post-operative data were recorded and were subsequently analyzed
22 at the end of the study period to prevent any bias or changes in the technique of the procedure.
23 Patients who had any secondary procedure that may affect the outcome were excluded such as

24 cholecystectomy or hiatal hernia repair. Also, patients who had Ondansteron (Zofran) ordered
25 around the clock or had other anti-emetic medication were excluded. The cohort was divided into
26 two groups based on the size of the bougie that was used. In the first 6 months of the study
27 period, all patients received a 32 fr. bougie during the SG (Group-1). In the second 6 months of
28 the study, all patients received a 36 fr bougie (Group-2). Endpoints included post-operative
29 hospital length of stay (LOS), nausea as determined by the amount of the anti-emetic
30 Ondansteron (Zofran) required, 30-day morbidity and mortality, and return to the ED. In
31 addition, percent excess weight loss (%EWL) at one month and at one year was analyzed. We
32 excluded patients whose post-operative order of anti-emetic was inadvertently placed around the
33 clock or did not have long-term data on weight loss.

34 The study was conducted in two facilities after Institutional Review Board approval: a
35 tertiary care hospital with teaching residency program and a small community hospital. These
36 procedures were shared between the surgical residents and the minimally invasive fellow at the
37 tertiary hospital and by the fellow only at the small community hospital. Data was analyzed
38 using Student's t-test and Pearson's chi-square using SPSS v. 22.0. A p-value of 0.05 or less
39 was considered to indicate statistical significance.

40

41 **TECHNIQUE:**

42 Since the operative technique can influence the surgical outcome, we used the same
43 procedure in all patients to minimize any variation that may influence this outcome. After
44 gaining access to the abdominal cavity using 5 incisions and 4 trocars, the short gastric vessels
45 were transected using Sonosurg ultrasonic device (Olympus, Tokyo-Japan) from the antrum to
46 the fundus of the stomach. A blunt tip bougie (size 32 fr first then 36 fr) was placed through the

47 esophagus and directed into the antrum. A stapler device 4.8 mm was used to transect the
48 stomach. We started at about 6 cm from the pylorus with a 45-degree angle on the stapler staying
49 about 2-3 cm from the incisura angularis. The stapler then hugs the bougie without stretching of
50 the stomach. We stayed at the edge of the gastric fat pad. The final cut was done leaving about 2
51 cm from the esophageal junction. We did not over sew the staple line, inverted, or placed sutures
52 at the crossing of the staples line to prevent narrowing of the gastric lumen.

53

54 **RESULTS:**

55 One hundred forty six patients underwent laparoscopic sleeve gastrectomy without a
56 concomitant procedure in one year; of these, 9 patients were excluded due to having an order for
57 around the clock Ondansetron (Zofran), and 6 patients were excluded due to inadequate long-
58 term data. The remaining 131 patients fit the inclusion criteria. Their data was recorded and
59 subsequently analyzed. Group-1 had 72 patients, and Group-2 had 59 patients. Both groups were
60 similar in age distribution and initial weight and body mass index (BMI). In addition, there was
61 no difference between the two groups in term of race, type of insurance or comorbidities (Tables
62 1&2)

63 There were no intra-operative complications or mortalities. In Group-1, one patient had a
64 liver biopsy and one patient had an excision of a thigh mass, while in Group-2 two patients had
65 liver biopsy and one patient had lysis of adhesions. Although these procedures were shared by
66 the surgical residents and the fellow of minimally invasive surgery, we felt that their
67 participation did not influence the outcome since the supervising attending is the responsible
68 party to keep the operation done in a similar fashion at all times. The same also applies to the
69 facility where these procedures were done based on referral and not pre-operative selection. In

70 addition the post-operative protocol was similar in both facilities and was supervised by the
71 attending surgeon. Group-1 had significantly longer hospital LOS (1.56 ± 0.82 vs. 1.32 ± 0.47
72 days, $p=0.04$). The use of Ondansetron for nausea was higher in group-1 than in group-2 but did
73 not reach statistical significance (6.7 ± 8.0 mg vs. 5.3 ± 4.5 mg, $p=0.2$ for group-1 and group-2
74 respectively).

75 Ten patients in Group-1 (13.9%) had at least one ED visit for complications (a total of 16
76 ED return visits) compared to five patients (8.5%) with one return visit each in Group-2
77 ($p=0.33$). In Group-1 six patients were readmitted from the ED vs. two patients in Group-2
78 ($p=0.23$). Of the six patients in Group-1 who were readmitted; 1 patient was readmitted once, 4
79 patients were readmitted twice and one was readmitted three times for a total of 57 days. In
80 contrast, the total readmission days for the two patients in Group-2 were 8 days. The mean
81 length of stay after readmission was longer in Group-1 vs. Group-2, although the difference was
82 not statistically significant (9.3 ± 4.7 vs. 5.0 ± 4.2 days $p=0.3$ respectively).

83 The reasons for return to the ED and hospital readmissions in Group-1 included post-
84 operative leak in two patients; one required re-operation and the second one was treated with
85 non-operative management by CT guided drainage and total parenteral nutrition. These two
86 leaks were in the proximal staple line. The other visits were because of nausea and dehydration
87 in three patients, wound infection in two patients, nonspecific abdominal pain in one patient, leg
88 pain in one patient and reflux in one patient. In Group-2, ED visits were a result of nausea and
89 dehydration in two patients, abdominal pain in one patient, wound seroma in one patient and
90 mesenteric vein thrombosis in one patient.

91 Percent excess weight loss (%EWL) at one month was significantly higher in Group-1
92 than in Group-2 ($13.6 \pm 4.9\%$ vs. $11.6 \pm 3.6\%$, respectively $p=0.007$), but there was no

93 statistically significant difference at one year between the two groups ($73.0 \pm 20.6\%$ vs. $71.1 \pm$
94 20.9% , $p=0.73$ for Group-1 and Group-2 respectively).

95

96 **DISCUSSION:**

97 Sleeve gastrectomy is gaining popularity as a stand-alone surgical weight loss
98 intervention with many advantages such as decreased operative time, relatively decreased
99 operative complexity and lack of placement of foreign body as in the laparoscopic banding
100 procedure. As these advantages are beneficial, there are some potential disadvantages such as
101 irreversibility and unproven long-term durability ⁽⁴⁾. Major factor affecting durability and
102 success of the SG is likely the issue of bougie size. It has been shown that bougie size of 40 fr.
103 and larger is associated with a statistically significant decrease in the post-operative leak rate ⁽⁵⁾.
104 It has also been shown, however, that 40 fr. bougie size significantly increases %EWL when
105 compared to 50 fr bougie size. Other studies have found no effect of bougie size on long-term
106 weight loss ⁽³⁾. Our results showed statistically significant difference in early %EWL at one
107 month, however, this was not the case after one year where this difference was not present and
108 could be due to the small sample size. Our results for weight loss after one year, however, were
109 more than 70% of the excess weight --higher than the reported results of 50% by Parikh ⁽³⁾. The
110 early reduction in %EWL was probably because of the restrictive effect of the smaller bougie
111 size on fluid and food intake, compounded with post-operative edema and swelling in the body
112 and fundus of the stomach resulting in more %EWL at one month.

113 Our main focus in our study was to evaluate the effect of bougie size in the immediate
114 post-operative period after SG. Our data show that the smaller bougie size did have a significant
115 effect on increasing post-operative hospital length of stay, which probably was, in part, due to

116 the increase in nausea. The fact that the use of anti-emetic medication did not reach statistical
117 significance could be because of low statistical power. The trend toward the increase use of this
118 medication, however, was evident indirectly (at least partially) in the increase in hospital LOS.
119 There may be other factors that also contributed to the longer length of stay. Additional support
120 for the negative effect of the smaller size bougie on the early post-operative morbidity, although
121 did not reach statistically significant difference due to small sample size, was the higher number
122 of ED return visits and hospital readmissions. These visits were mainly due to dehydration and
123 persistent nausea possibly secondary to the narrow tube of the stomach combined with post-
124 operative edema resulting in the need for intravenous fluid supplement and control of the nausea.
125 In addition, smaller bougie size did result in more leaks than the larger bougie size confirming
126 the finding of Atkins et al ⁽⁵⁾. This in turn could be because of the increase in pressure by the
127 narrowed body of the stomach creating an increased pressure area on the proximal staple line
128 resulting in this leak. However, this finding was also not statistically significant due to our small
129 study size.

130 It is not clear why the small change in the bougie caliber of 4 fr. (1.33 mm) would create
131 this difference in outcome except that the post-operative edema may be a contributing factor.
132 However, from personal experience in filling lap-bands, we see a difference when 0.2 or 0.5 cc
133 of fluid can create near obstructive symptoms of the band.

134 In order to overcome the non-contemporaneous nature of our study we elected not
135 analyze the data until the end of the study period to prevent any bias in changing the surgical
136 technique especially in the distance from the pylorus or staying away more from the incisura
137 angularis, which could be one of the reasons in creating a higher-pressure zone thus affecting the
138 outcome. In addition to the above factor, we recognize that the involvement of residents and

139 fellow and the two different facilities may be a limiting factor, however we don't believe that
140 this should influence the outcome as long as the operation was done in the same manner and no
141 bias in patients selection to the institutions as proven by our data. A larger randomized control
142 studies with different bougie sizes and controlling other technical variations would be beneficial
143 to standardize the operation and reach the best technique to improve patients' outcome.

144

145 **CONCLUSION:**

146 Our data support the fact that bougie size used during SG does not affect the long-term
147 %EWL with >70 % reduction in the excess weight after one year. It indicates, however, that the
148 smaller size bougie resulted in a significant increase in hospital length of stay. The other findings
149 of increase in nausea with increase in 30-day morbidity and returns to the ED with increase in
150 readmission rate did not reach statistical significance likely due to the small sample size. Further
151 studies are needed to confirm these observations for procedural optimization regarding the
152 proper bougie size and hopefully improvement in patients' outcome.

153

154

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Table 1: Pre-operative Data

		Group 1 (number =72)	Group 2 (number =59)	<i>p-value</i>
	Age (yrs.)	44.0 ± 12	45.6 ± 12	0.46
	Weight (lbs.)	289 ± 60	285 ± 59	0.74
	BMI (kg/m ²)	47.5 ± 8.3	46.5 ± 7.3	0.73
Race	White	70.8% (51)	79.7% (47)	0.247
	Black	29.2 (21)	20.3% (12)	
Insurance	Commercial	90.3% (65)	86.4% (51)	0.773
	Medicare	4.2% (3)	5.1% (3)	
	Medicaid	5.6% (4)	8.5% (5)	

Table 2: Comorbidities

	Group 1	Group 2	P Value
Hypertension	52.8% (38)	59.3% (35)	0.453
Diabetes	26.4% (19)	33.9% (20)	0.35
Sleep Apnea	27.8% (20)	27.1% (16)	0.933
Hyperlipidemia	27.8% (20)	37.3% (22)	0.246
Reflux	36.1% (26)	50.8% (30)	0.09
Arthritis	29.2% (21)	25.4% (15)	0.633
Asthma	15.3% (11)	11.9% (7)	0.572
CAD/MI	4.2% (3)	6.8% (4)	0.508
Depression	6.9% (5)	8.5% (5)	0.743
Fibromyalgia	2.8% (2)	1.7% (1)	0.68

DISCUSSION: DR. ARTHUR CARLIN (Detroit, Michigan): My first question really relates to other technical details of the procedure that may have impacted outcomes in this study. So I'd like you to comment on, the distance from the pylorus that the staple line was created from or started. How was the stapler applied immediately adjacent to the orogastric tube and maybe some slight -- some predetermined distance? And what about the stable line? Some people implicate the staple line and that would narrow the sleeve even further.

My second group of questions is regarding the similarity of two cohorts. You state in your manuscript that the two groups were similar with respect to age, weight and BMI, but what about other factors, like race, comorbidities, medication use and insurance status, which have been shown to affect outcome. Also, these operations are performed at two different facilities, a tertiary care hospital with their teaching residency program, as well as in a small community hospital. And I'm just curious how many cases with each bougie size were done at each hospital and were there any differences in outcome based on location of the operation? And what about the resident assisting? Was this similar both places and how about the discharge protocols, were they similar and how did you make sure they were maintained equally at both places? My final question has to do with Ondansetron use as a surrogate marker for nausea. What about other antiemetics? Nausea is a very common complication of the surgery. Residents get called in the middle of the night and they will get different alternatives to try and help the patients. And were steroids given intraoperatively to any of the patients by anesthesia to decrease postop nausea? And, finally, what about your fluid protocols both intraoperatively and postoperatively as

dehydration can also lead to nausea.

DR. VAVRA: For the procedure, the stapler was initially applied at the incisura angularis, usually about 6 to 8 centimeters from the pylorus, at a 45-degree angle as to not narrow the initial part of the staple line. We stapled close to the bougie but not so that there was too much tightness for the sleeve. And for your second group of questions, the preoperative comorbidities of all the patients were very similar. We did not include insurance in our preoperative evaluation as the patient population is very similar for this. The patient population at both hospitals was similar. As for the Zofran use, any patient who received anything other than Zofran was excluded from the study. There were no medicines that were allowed to be given without the surgeon being aware. If so, then they were also excluded from the study. This service does also have a fellow. And the fellow and residents were present in the surgery, however, the mentoring surgeon was the main operator for all the surgeries so that the surgery technique did not change. And for our postoperative dehydration, to monitor this with our patients, we did normal fluid resuscitation and followed the urine output in the hospital. As for the patients when they went home from the hospital, obviously, we believe there was more dehydration in the 32 French group due to the increased pressure and decreased food intake from the smaller sleeve size.

DR. JAMES MADURA (Scottsdale, Arizona): One of the most frustrating things about bariatric surgery is every year at the bariatric meeting we get five papers that say bigger is better, smaller is better, different anastomosis size, and this is just another one of those series that I would caution anybody of taking anything away from this. When you

consider one French is one-third of a millimeter, you're talking about a 4 French difference in your bougie size, which is just over 1 millimeter. So whether that's a technical difference, I would find it very hard for you to explain any reason why a 1 millimeter difference in bougie size has any effect on immediate complications. And long-term outcomes, the effect on volume, if you consider the volume of a cylinder as $\pi r^2 h$, a 1 millimeter difference in the radius of this pouch that you're creating has very little difference in volume, so long-term effects on weight loss or any restriction are negotiable, as well.

DR. PETER HALLOWELL (Charlottesville, Virginia): I think James stole part of my question on the size of the bougie, but looking at the size, what's physiologically going on with the sleeve? Are we talking about restriction? Or are we talking about some other physiologic mechanism that is making the weight loss?

DR. VAVRA: Well, for our study we believe that it was due to the smaller size. I know it didn't make a huge difference in this French, because it's actually small when you analyze a 4 French difference. However, because of our sample size, there may have been more negative outcomes in the larger French group had we had more patients involved in the study, and I think that now we're also using the 40 French. I think that we need to analyze that even further, and if we are going to have similar long-term outcomes, maybe because of our sample size, the 36 French and the 32 French actually would have been very similar if we would have had more patients involved in the study. And increasing the size of the bougie will hopefully decrease the short-term negative effects and still have the same long-term weight loss effects for our patients.

DR. JAMES R. DeBORD (Peoria, Illinois): But was there, in fact, any difference in the two groups in terms of the two main complications of this operation; Severe reflux and sleeve gastrectomy leaks? And, secondly, I didn't really hear your answer to the initial discussion about whether you imbricated or reinforced your staple line.

DR. VAVRA: Correct. We did not reinforce. We did over sew or do anything to the staple line. It was staples alone, just due to, that would make the sleeve smaller, even after the 32 French bougie. So that would decrease the size even more. So we did not over sew our staple line. As for the leaks, there was no statistical significant difference, however, these complications were more common amongst the 32 French group and, again, this is due to our low sample size. It could been very different had we had more patients involved in the study.