Evaluation of the Swedish adjustable gastric band VC (SAGB-VC) in an Australian population: early results

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Accepted for publication
June 14, 2011

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DOI: 10.1503/cjs.011511

Background: The Swedish adjustable gastric band VC (SAGB-VC) has been in use in Australia since 2007. We evaluated its efficacy and safety.

Methods: We retrospectively analyzed the prospective clinical data of patients who received the implant between November 2007 and June 2009 at 3 Australian bariatric centres.

Results: In all, 1176 patients (mean age 45.9 [standard deviation (SD) 12.3] yr, mean body mass index 43.4 [SD 7.6]) received the SAGB-VC. At a mean follow-up of 11 (SD 3) months, weight reduced by a mean of 18.4 (SD 11.1) kg with an excess weight loss of 37.8% (SD 19.9%). Body mass index decreased (from mean 43.4 [SD 7.7] to mean 36.7 [SD 6.5], $p < 0.001$). Type 2 diabetes (T2DM) was reported in 167 patients and hypertension in 373. Improvement occurred in 73.5% of patients with T2DM and 31% with hypertension, with patient-reported reduction or cessation of medication. Metabolic syndrome indices improved during follow-up: high-density lipoprotein cholesterol (mean 1.3 [SD 0.3] v. mean 1.4 [SD 0.3] mmol/L, $p < 0.001$), triglycerides (mean 1.6 [SD 0.8] v. mean 1.3 [SD 0.7] mmol/L, $p < 0.001$), waist circumference (men 141 [SD 103] to 121 [SD 15] cm, women 117 [SD 14] to 105 [SD 14] cm, both $p < 0.001$), C-reactive protein (90.5 [SD 75.2] v. 53.3 [SD 61.9] nmol/L, $p < 0.001$). The complication rate was 4.2%.

Conclusion: The SAGB-VC is safe and effective for treating obesity and its comorbidities. The results are reproducible in separate Australian centres and consistent with published literature.

Contexte : On utilise l'anneau gastrique ajustable suédois VC (AGAS-VC) depuis 2007. Nous avons évalué son efficacité et son innocuité.

Méthodes : Nous avons analysé de manière rétrospective les données cliniques prospectives concernant les patients ayant reçu l'implant entre novembre 2007 et juin 2009 dans 3 centres bariatriques australiens.

Résultats : En tout, 1176 patients (âge moyen 45,9 [écart-type (ET) 12,3] ans, indice de masse corporelle moyenne 43,4 [ET 7,6]), ont reçu le dispositif AGAS-VC. Après un suivi moyen de 11 (ET 3) mois, le poids avait diminué en moyenne de 18,4 (ET 11,1) kg, avec une perte d'exédent de poids de 37,8 % (ET 19,9 %). L'indice de masse corporelle a diminué (d'une moyenne de 43,4 [ET 7,7] à une moyenne de 38,7 [ET 6,5], $p < 0{,}001$). Le diabète de type 2 (DT2) avait été signalé chez 167 patients et l'hypertension, chez 373 patients. On a observé une amélioration chez 73,5 % des patients atteints de DT2 et chez 31 % des patients atteints d'hypertension, avec réduction ou arrêt des médicaments déclarés par les patients. Les indices de syndrome métabolique se sont améliorés durant le suivi : cholestérol à lipoprotéines de haute densité (moyenne 1,3 [ET 0,3] c. moyenne 1,4 [ET 0,3] mmol/L, $p < 0{,}001$), triglycérides (moyenne 1,6 [ET 0,8] c. moyenne 1,3 [ET 0,7] mmol/L, $p < 0{,}001$), tour de taille (hommes, de 141 [ET 103] à 121 [ET 15] cm; femmes, de 117 [ET 14] à 105 [ET 14] cm, tous $p < 0{,}001$), protéine C réactive (90,5 [ET 75,2] c. 53,3 [ET 61,9] nmol/L, $p < 0{,}001$). Le taux de complications a été de 4,2 %.

Conclusion : Le dispositif AGAS-VC est sécuritaire et efficace pour le traitement de l'obésité et de ses comorbidités. Les résultats sont reproductibles dans différents centres australiens et concordent avec les résultats publiés dans la littérature.

Obesity is a substantial public health problem, and bariatric surgery is increasingly used to treat morbid obesity. The laparoscopic placement of an adjustable gastric band is the least invasive bariatric surgery technique.[1] The technique is safe, as shown in a meta-analysis by Buchwald and colleagues,[2] which included data from 22 094 patients and reported an operative mortality of 0.1% for restrictive procedures. Bariatric surgery is also effective in decreasing obesity-related comorbidities.[3] In a review of the impact of bariatric surgery on type 2 diabetes, Dixon[4] reported that the sustained weight loss achieved was associated with remission of type 2 diabetes in 50%–85% of patients. Technological advances have led to changes in the devices used, and a new generation of the Swedish adjustable gastric band, the SAGB-VC (REALIZE), has been in use in Australia since 2007.[5] The purpose of this study was to evaluate the safety and efficacy of the REALIZE SAGB-VC in the treatment of morbid obesity in 3 separate centres in Australia.

Methods

This was a retrospective analysis of data at 1 year after implantation of the SAGB-VC in patients with morbid obesity who received the implant between November 2007 and June 2009. Patient records at 3 clinics in Australia based in Adelaide, Sydney and Perth were reviewed and data extracted before implantation and 12 months after. The patients were treated under similar protocols at the 3 sites. Prior to the surgery, patients with severe truncal obesity were placed on a very low-calorie meal replacement diet to reduce liver size. The surgery was conducted laparoscopically and the band inserted using the pars flaccid technique. Patients with a hiatus hernia also underwent crural repair. In selected patients with a large fat pad adjacent to and potentially obscuring the gastresophageal junction, the pad was removed or reflected to facilitate gastrogastric serosa-to-serosa apposition of 2–3 anterior permanent sutures to secure the gastric band in place. In 4- to 6-week intervals postsurgery, patients attended follow-up visits during which their weight loss progress was monitored and the volume of fluid in the band adjusted as required. The goal was to achieve at least 0.5–1 kg of weight loss per week. All patients also met with a dietitian before and after the surgery for advice on diet and how to select food after receiving an adjustable gastric band. Weight was measured using electronic scales at baseline and at follow-up and recorded in the medical record. We determined weight loss by calculating the difference between weight at entry into the clinic and weight at final follow-up. Weight loss, percent excess weight loss (%EWL) and changes in body mass index (BMI) were collated. We determined excess weight by calculating the difference between actual weight and weight at a BMI of 25, and %EWL was calculated using that value. The changes in weight are reported according to preoperative BMI, sex and age. Complication rates, including the rates of revision surgery, port infections, erosion and slippages, were collated. Patients were seen at follow-up to determine weight change, and comorbidity improvement and remission were assessed via patient self-report for the following conditions: type 2 diabetes mellitus, hypertension, hyperlipidemia, gastroesophageal reflux disease, sleep apnea, depression and joint and back pain. Laboratory results where available were extracted and collated. The treatment of comorbidities remained the responsibility of the patients' primary care physicians.

To be included in the study, patients had to be 18 years or older and had to meet the National Health and Medical Research Council criteria for surgery of BMI greater than 35 with 1 or more comorbidities or BMI greater than 40.

The Bellberry Human Research Ethics Committee approved this study, and patients provided written informed consent to the use of their data. The study was registered with the Australia and New Zealand Clinical Trial register (ANZCTR) No ACTRN12610000137099.

Statistical analysis

Categories of BMI were defined as 40 or less, 40.1–49.9 and greater than 50. Age categories were defined as younger than 30 years, 30–39, 40–49 and 50 years or older. We assessed changes from baseline using repeated-measures analysis of variance, and χ^2 analysis was used to detect differences for medication use before surgery and at follow-up. Sex was included as a factor in the analysis. We considered results to be significant at $p < 0.05$. Data are reported as means and standard deviations (SD). Statistical analysis was performed using PASW Statistics version 18 (SPSS). When data were incomplete, only the available data were included in our analyses.

Results

We pooled the results from the 3 Australian centres, as all 3 have similar protocols for follow-up, using a multidisciplinary approach that includes surgeons, bariatric practitioners, nurses, dietitians, psychologists and physical therapists.

Between November 2007 and June 2009, 1176 patients had an SAGB-VC implanted. The mean baseline characteristics were age 45.9 (SD 12.3) years, BMI 43.4 (SD 7.6) and excess weight 51.4 (SD 21.2) kg.

Postoperative complications

There were no deaths within 30 days of the procedure or conversions to an open approach in this series. Postoperative wound infections occurred in 11 patients: 9 required removal and later replacement of the injection port and 2 required removal of the SAGB-VC. Port revision

occurred in 20 patients, catheter revision in 11 and proximal band slippage in 1. There were no erosions. Three patients had the SAGB-VC removed at their request. Patients with 6 months or less of follow-up were excluded from further analysis.

At a mean follow-up of 11 (SD 3) months (n = 1056; 775 women and 281 men), weight reduced by 18.4 (SD 11.1) kg with a %EWL of 37.8% (SD 19.9%), and mean BMI fell from 43.3 (SD 7.6) to 36.7 (SD 6.7; $p < 0.001$). Women had a greater %EWL than men (38.8% [SD 20.0%] v. 35.0% [SD 19.1%], $p = 0.009$), but this was confined to the lowest BMI category (≤ 40; Table 1).

Age had no effect on BMI or %EWL (Table 2). Patients with a BMI of 40 or less at baseline had greater %EWL than patients with a BMI greater than 40 (43.2% [SD 22.4%] v. 33.9% [SD 17.0%], $p < 0.001$).

Waist circumference decreased (men: n = 155, 133 [SD 15] to 119 [SD 14] cm, $p < 0.001$; women: n = 451, 117 [SD 15] to 105 [SD 14] cm, $p < 0.001$).

Comorbidities

Type 2 diabetes was reported in 167 (16%) patients (Table 3). At follow-up, blood glucose had decreased from 8.3 (SD 3.2) to 7.3 (SD 3.7) mmol/L ($p < 0.001$). The proportion of patients requiring medications also decreased from 31% to 22% ($p = 0.012$), and the average number of doses required per day decreased from 1.6 (SD 0.7) to 1.1 (SD 0.8; $p < 0.001$).

Hypertension was reported in 373 (35%) patients (Table 3). Mean systolic blood pressure decreased from 144 (SD 25) to 128 (SD 14) mm Hg, and mean diastolic blood pressure decreased from 86 (SD 13) to 77 (SD 13) mm Hg (both $p < 0.001$). The average number of medication doses required per day decreased significantly (1.6 [SD 10] v. 1.1 [SD 1.0], $p < 0.001$).

Weight loss was associated with resolution or improvement of the following comorbid illnesses: hyperlipidemia, gastroesophageal reflux disease, obstructive sleep apnea, depression, and joint and back pain (Table 3).

Biochemical variables

Biochemical variables are presented in Table 4. There were improvements in glucose and insulin concentrations, liver function tests (except bilirubin) and C-reactive protein. Total and low-density lipoprotein cholesterol concentrations were increased at follow-up (0.3 [SD 2.8] mmol/L, $p = 0.044$ and 0.1 [SD 0.7] mmol/L, $p = 0.001$, respectively).

Table 1. Percent excess weight loss (%EWL) by body mass index (BMI) and sex

BMI	Sex	%EWL, mean (SD)	No.
< 40	Female	44.5 (22.1)	326
	Male	39.1 (22.8)	100
40.1–49.9	Female	35.3 (18.0)	339
	Male	32.5 (16.6)	153
> 50	Female	32.8 (15.0)	132
	Male	31.5 (14.3)	46

SD = standard deviation.

Table 2. Percent excess weight (%EWL) loss by body mass index (BMI) and age

BMI	Age, yr	%EWL, mean (SD)
< 40	< 30	47.3 (26.3)
	30–39	42.9 (23.0)
	40–49	40.9 (21.7)
	≥ 50	44.4 (21.7)
40.1–49.9	< 30	36.6 (18.5)
	30–39	33.0 (21.6)
	40–49	34.8 (17.8)
	≥ 50	34.1 (14.6)
> 50	< 30	37.2 (18.0)
	30–39	33.3 (15.2)
	40–49	29.8 (15.4)
	≥ 50	32.8 (12.4)

SD = standard deviation.

Table 3. Self-reported comorbidities before and after weight loss

Comorbidity	Before, no.	After, no. (%)
Type 2 diabetes	167	35 (21) remission 87 (52) improved 40 (24) unchanged 3 (2) deteriorated
Hypoglycaemic agents	142 40 on insulin	22 (15) ceased medication 14 (35) ceased insulin
Hypertension	373	101 (27) resolved 127 (34) improved 138 (37) unchanged 7 (2) deteriorated
Antihypertensive drugs	313 118 ≥ 2 medications	53 (17) ceased medication 75 (64) ≥ 2 medications 2 (< 1) started medication
Hyperlipidaemia	270	35 (13) resolved 73 (27) improved 124 (46) unchanged 8 (3) deteriorated
Gastresophageal reflux disease	328	180 (55) resolved 43 (13) improved 49 (15) unchanged 7 (2) deteriorated
Sleep apnea	209	42 (20) resolved 52 (25) improved 65 (31) unchanged 2 (1) began
Depression	306	37 (12) resolved 73 (24) improved 138 (45) unchanged 12 (4) deteriorated
Joint and back pain	408	49 (12) resolved 106 (26) improved 175 (43) unchanged 12 (3) deteriorated

Discussion

The main finding of this study conducted at 3 centres in Australia was that the SAGB-VC was safe and effective in the treatment of obesity and its comorbidities. The SAGB-VC has an improved locking mechanism and a soft circumferential compressing chamber that may be adjusted by introducing normal saline via a low-profile injection port. It is thought that the new design may provide better control of restriction and that it may be associated with fewer perioperative and postoperative complications. Whereas this study did not prospectively compare this SAGB with previous models, it does allow comparison with published data on the previous models used by the same group of clinicians under a similar clinical protocol. When compared with previous models of the SAGB, the SAGB-VC is equally safe and has few associated perioperative complications.[6] At follow-up, the prevalence of band slippage was very low (0.1%), and there were no erosions. The rate of port site infection was 1%, which is consistent with previously published results.[7] Port site infection is a persistent problem for patients with an adjustable gastric band, despite perioperative antibiotics and application of standard measures of antisepsis before, during and after surgery. Obesity is associated with a greater chance of wound infection,[8] and the insertion of foreign material, such as an injection port, provides a nidus for the infection. Whereas wound infection is a major impediment for the patient, it has not been a life-threatening complication; in all but 2 patients the infections were treated using local measures. In patients in whom the band needed to be removed, the infection had extended beyond the abdominal wall to involve the band itself. This uncommon event has previously been reported at a similarly low rate.[9]

A %EWL of 38% at 1-year follow-up is consistent with the results of other studies on the SAGB.[5,6,10,11] As reported in previous studies, younger women lose weight faster than older women. However, the SAGB-VC is effective in all age groups, both sexes and all BMI categories. Previous studies from our group and others have reported similar findings and support the view that the SAGB-VC can be used in men and women of all ages and indicated BMI levels.[6,12,13] Studies from other centres have reported greater %EWL than the present study. Suter and colleagues[14] reported an EWL of 55% at 1-year follow-up; however, patients in that study were younger women, a group in which we have also observed better weight loss outcomes. Gravante and colleagues[15] reported a %EWL of 48.2% after 1 year in a study comparing 2 different devices, with no difference in weight loss between the groups. The reasons for the difference in weight loss reported between the present study and previous ones are unclear, but may be explained by the variability of %EWL achieved based on differences in defining ideal body weight.

An important outcome of the present study was that waist circumference reduced significantly. Waist circumference can be used clinically to identify patients with excess visceral adipose tissue, which is a risk factor for cardiovascular disease.[16] In the Swedish Obesity Study, waist circumference was positively associated with mortality,

Table 4: Biochemical variables before and after weight loss

Variable (reference range)	No. of patients	Value, mean (SD) Before	After	*p* value
Glycemic status				
Glucose, mmol/L (3.0–5.4 mmol/L)	257	6.1 (3.5)	5.6 (3.3)	< 0.001
Insulin, mU/L (4–10 mU/L)	104	26.3 (44.4)	13.9 (17.0)	< 0.001
Liver function				
γ-Glutamyltransferase, μkat/L (men: < 0.8 μkat/L, women: < 0.5 μkat/L)	272	0.6 (0.5)	0.4 (0.5)	< 0.001
Alkaline phosphatase, μkat/L (0.4–1.7 μkat/L)	278	1.4 (0.4)	1.2 (0.4)	< 0.001
Aspartate aminotrasferase, μkat/L (< 0.7 μkat/L)	275	0.5 (0.3)	0.3 (0.2)	< 0.001
Alanine aminotransferase, μkat/L (< 0.6 μkat/L)	277	0.7 (0.4)	0.4 (0.2)	< 0.001
Bilirubin, umol/L (< 20 μmol/L)	151	9.8 (4.5)	11.1 (5.4)	< 0.001
Lipids, homocysteine and C-reactive protein				
Triglyceride, mmol/L (< 1.7 mmol/L)	261	1.6 (0.8)	1.3 (0.7)	< 0.001
Total cholesterol, mmol/L*	277	4.9 (1.1)	5.3 (2.9)	0.044
High density cholesterol, mmol/L (1.0–2.2 mmol/L)	249	1.3 (0.3)	1.4 (0.3)	< 0.001
Low density cholesterol, mmol/L (2.0–3.4 mmol/L)	243	3.0 (1.0)	3.1 (1.0)	0.001
Homocysteine, μmol/L (5–15 μmol/L)	94	13.9 (16.6)	14.5 (10.6)	< 0.001
C-reactive protein, nmol/L (0.76–28.5 nmol/L)	216	90.5 (75.2)	53.3 (61.9)	< 0.001
Leucocytes				
White blood cell count, 10^9/L (mean 7.5 [SD 3.5])	153	6.9 (1.9)	6.5 (1.9)	0.013
Neutrophils, 10^9/L (2–7.5 10^9/L)	151	4.1 (1.5)	3.7 (1.4)	0.003

SD = standard deviation.
*For minimal risk of coronary artery disease, the Australian National Heart Foundation recommends a treatment target of < 4.0 mmol/L.

with a 25% increase in mortality per 10 cm increase in waist circumference.[17]

Comorbidities of obesity are significantly improved as a result of the weight loss achieved during the postoperative period. Most patients in the present study who had type 2 diabetes or hypertension were able to discontinue or significantly reduce their medication use as a result of the procedure and subsequent weight loss. These findings are consistent with results from previous studies from our group and others.[18–21] Overall, there were improvements in cardiovascular disease risk factors, including blood pressure, high-density lipoprotein cholesterol and triglycerides. However, there were significant increases in total and low-density lipoprotein cholesterol that were unexpected. Dixon and O'Brien[21,22] found no change in total and low-density lipoprotein cholesterol, with an overall favourable change in lipid levels in patients with and without diabetes. In a systematic review, Poobalan and colleagues[23] reported that for every 10 kg of weight loss, a drop of 0.23 mmol/L in cholesterol could be expected. We speculate that changes in lipid-lowering medication that could not be fully quantified in a retrospective analysis may be responsible for the increases observed in our study. Although the increase was modest, it emphasizes the need for continued monitoring of cardiovascular disease risk factors.

We observed a 40% reduction in C-reactive protein levels, but there was a significant increase in homocysteine that was within the normal range. Raised concentrations of C-reactive protein and homocysteine are thought to be emerging risk factors for cardiovascular disease.[24] Weight loss usually brings about reductions in C-reactive protein and homocysteine.[25] Dixon and colleagues[26] reported a similar phenomenon and suggested that higher serum folate and vitamin B12 levels may be required to maintain homocysteine concentrations. Weight reduction was associated with improvements in liver function tests within the normal range, which we believe reflects a reduction in liver fat. We have previously reported reductions in liver fat after surgery associated with a change in liver enzymes.[27] Weight reduction was also associated with improvement in sleep apnea, polycystic ovarian syndrome, joint symptoms, depression and gastroesophageal reflux disease. These findings are consistent with results from previous studies from our group.[3] To our knowledge, the present study is the largest series assessing this device; 1 other published study involved 82 patients.[28]

Conclusion

The newly developed SAGB-VC is safe and effective for the treatment of obesity. Significant weight loss and improvement in comorbid illnesses occurred after a relatively short follow-up period of 11 months, which is consistent with best practice outcomes and, as previously noted in other studies, should form the basis for long-term control of obesity and its associated comorbid illness.

Funding: This was an investigator-initiated study. Partial financial support was provided by Ethicon Endo-Surgery Inc. Grant No. 2925

Competing interests: None declared for J.B. Keogh, S. Taylor and S. Wahlroos. As above for A. Brancatisano, F. McDonald, R. Brancatisano, J. Chisholm, L. Kow, B. Ryan and J. Toouli. J.M. Hamdorf declares having received consultancy fees from Allergan and travel assistance from Johnson and Johnson.

Contributors: J.B. Koegh, A. Bransatisano, R. Brancatisano, L. Kow, B. Ryan and J. Toouli designed the study. J.B. Koegh, A. Bransatisano, S. Taylor, F. McDonald, J.M. Hamdorf, L. Kow and S. Wahlroos undertook data extraction. J.B. Koegh, A. Bransatisano, F. McDonald, J.M. Hamdorf, J. Chisholm and J. Toouli undertook data analysis. J.B. Koegh and J. Toouli wrote the manuscript. All authors critically reviewed it and approved publication.

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