Perioperative Factors Affecting Ambulatory Outcomes Following Laparoscopic-Adjustable Gastric Banding

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Abstract

Objective: Morbidly obese patients are traditionally hospitalised following bariatric surgery. However, laparoscopic-adjustable gastric banding (LAGB) is amenable for ambulatory care. We hypothesised that the majority of patients can receive an ambulatory LAGB and that both surgical and anaesthetic perioperative factors will significantly affect non-ambulatory LAGB outcomes.

Methods: Medical records of 201 consecutive LAGB patients performed at the University of Kansas Medical Centre during a 3-y period were reviewed. Demographic, medical, laboratory, anesthetic, intraoperative and postoperative data were collected. Factors associated with non-ambulatory outcomes were identified and analysed using logistic regression, and a classification tree analysis was used to rank the descriptive model factor to the non-ambulatory outcome.

Results: Average patient age was 43.4±11.4 years, and average body mass index was 48.2±10.3 kg m⁻². A total of 155 patients (77.1%; 95% confidence interval, 71%–83%; p=0.0001) were discharged home within 2–3 hours of surgery, whereas 36 stayed for 23 hours and 10 required hospital admission for 1–2 days. Increased surgical port numbers (p=0.007), ≥50% of total intraoperative fentanyl administered in the recovery room (post-anaesthesia care unit) for the treatment of postoperative pain (p=0.007) and a lack of prophylactic beta-blockade (p=0.001) were three factors associated with non-ambulatory outcomes. Obstructive sleep apnoea was not associated with a non-ambulatory outcome (p=0.83).

Conclusion: The majority of patients received an ambulatory LAGB. Meticulous laparoscopic surgical technique with the least feasible number of access ports and multimodal analgesic technique aimed at reduction of postoperative opioid consumption are the most important factors for a successful ambulatory LAGB outcome.

Keywords: Ambulatory surgery, bariatric surgery, laparoscopic surgery, outpatient surgery


Bulgular: Çalışmada hasta yaş ortalaması 43,4±11,4 yıldır ve vücut kitle indeksi ortalaması 48,2±10,3 kg m⁻² olarak bulundu. Toplam 155 hasta ameliyat sonrası 2-3 saat içerisinde evlerine taburcu edildiken, 36 hasta yatırılarak 23 saat hastanede tutuldu ve 10 hastanın 1-2 gün boyunca hastanede yatış gerektirir. LAGB sonrası hastanın yatışa giden diğer faktör; ikişek cerrahi port sayısı (p=0,007), intraoperatif kullanılan fentanil miktarının %50’den fazlasının uyanma odasında postoperatif ağrı tedavisi için kullanılması (p=0,007) ve profilaktik beta blokaj uygulanmaması (p=0,001) olarak saptandı. Obstruktif Uykü Aşırı Sendromu hastanın yatışa giden diğer faktör bunludur (p=0,83).


Anahtar Sözcüklər: Ambulatuvar cerrahi, bariatrik cerrahi, laparoskopik cerrahi, günlük ambulatuvar
Introduction

Morbidly obese patients undergoing bariatric surgery are considered at an increased risk for perioperative complications and are frequently hospitalised (1). Since cost containment is an important issue in contemporary health care, there is an incentive to extend performance of feasible surgical procedures to the ambulatory care setting. Ambulatory surgery is attractive to patients due to increased feelings of being in control of their lives, expedient services and avoidance of potential risks related to hospitalisation. In general, the presence of co-existing diseases, the invasiveness of surgery, intraoperative complications and recovery issues guide the decision about ambulatory outcome (2). Advent of technology has promoted the development of less invasive surgical techniques, and some non-ambulatory procedures have been converted to ambulatory procedures. Laparoscopic-adjustable gastric banding (LAGB) is a minimally invasive bariatric surgery with a low incidence of perioperative complications (2, 3). Several trials have demonstrated that careful patient selection allows LAGB to be an ambulatory procedure (4-10). However, many of these prospective studies had small sample sizes with patients already preselected in observational trials. There was no attempt to identify factors contributing to non-ambulatory outcomes. We hypothesised that the majority of patients could receive an ambulatory LAGB and that both surgical and anaesthetic perioperative factors would affect non-ambulatory LAGB outcomes. Identification of these factors may help select patients preoperatively, determining the most sensible venue for performance of LAGB surgery and guiding where patients go postoperatively. To test this hypothesis, we conducted a retrospective review of all patients undergoing LAGB at the University of Kansas Medical Center during a 3-y period.

Methods

The Institutional Review Board approved this retrospective study and waived the requirement for a written informed consent. This study included LAGBs performed by a single surgeon at the University of Kansas Medical Center over a 3-y period. The surgeon’s database was used for patient identification. Once the patient list was established, a review of perioperative medical records followed. All available relevant preoperative, intraoperative anaesthetic and surgical data as well as postoperative data were collected by the primary investigator and a research assistant. Preoperative data included demographic characteristics, co-existing diseases, outpatient medications, physical examination data and American Society of Anesthesiologists physical class. Anaesthetic data included type of induction, drugs administered, airway management technique, number of intubation attempts and intraoperative anaesthetic management details (hemodynamic variables, volatile agents, opioids, nonsteroidal analgesics, antiemetic drugs and type and amount of intravenous fluids). Surgical data collected included number of access ports, band size, length of surgery, blood loss and complications. Post-anaesthesia care unit (PACU) data incorporated type and amount of analgesic and antiemetic drugs administered, amount of fluids, length of PACU stay, indications for delayed recovery or hospital admission, patient disposition, timing of patient’s discharge and the reason for 23-hour stay or hospital admission. The follow-up was limited to 30 days post-procedure.

Procedural description

All patients received intravenous (IV) midazolam premedication and prophylactic antibiotics. Deep venous thrombosis prophylaxis was provided through subcutaneous administration of 40 mg of enoxaparin. Per surgeon’s protocol, a single dose of 25-50 mg of oral metoprolol was administered upon arrival to the hospital to patients aged ≥40 y with no medical contraindications to beta blockade. For some patients, oral metoprolol was indicated per protocol, but preoperative administration was missed. In those cases where oral metoprolol had not been administered preoperatively, 5 mg of IV metoprolol was administered intraoperatively as a substitute for the intended dose of oral metoprolol. All patients received rapid sequence induction using propofol and either succinylcholine or rocuronium. Two patients who required more than two intubation attempts by trainees were subsequently intubated by attending anaesthesiologists using direct laryngoscopy and the Eschmann tube introducer. Intraoperative anaesthetic technique included inhalational agents (desflurane, sevoflurane or isoflurane), non-depolarising muscle relaxants (rocuronium or vecuronium) and IV boluses of fentanyl. Patients without medical contraindications to ketorolac received 30 mg of this nonsteroidal analgesic by IV. Lactated ringers and 0.9% sodium chloride solution were the only types of fluids used. All patients received IV ondansetron, and those with no diagnosis of diabetes mellitus also received 4 mg of IV dexamethasone for prophylaxis of postoperative nausea and vomiting. The attending surgeon performed all LAGBs paired with several residents. Depending on the difficulty of laparoscopic access, two to four surgical access ports were created. Using the pars flaccida technique, a LAP-BAND AP™ System (Adjustable Gastric Banding System with OMNIFORM™ Design, Allergan, Santa Barbara, CA, USA) was placed with no conversions to an open procedure. All surgical ports and incisions were infiltrated with 0.25% bupivacaine following LAGB placement. The depth of the neuromuscular block was monitored using the train-of-four ratio, and all patients were routinely reversed with a combination of IV neostigmine and glycopyrrolate. All patients were successfully extubated in the operating room. Use of IV fentanyl for the treatment of postoperative pain was routine practice. PACU nurses were given an initial order to administer up to 200 mg of fentanyl in doses of 25-50 mg every 5-10 min until a satisfactory pain score on a 1-10 scale was achieved. The Aldrete score and the modified Aldrete score were assessment tools for evaluation of patient readiness for discharge (11). An Aldrete score of 10 was mandatory for patient transfer from the PACU to Phase II recovery. A minimum modified Aldrete score of 13.
was required before a patient could be discharged from the hospital. The final clinical decision about the discharge was made after consultation between the anaesthesia and surgical teams. Home pain medication included a combination of oral hydrocodone and acetaminophen. In addition to general discharge instructions, specific instructions were provided concerning the maximum dosage of hydrocodone, avoidance of alcoholic beverages, immediate physical availability of a responsible adult in the first postoperative night and mandatory use of a continuous positive airway pressure device while asleep for patients with obstructive sleep apnoea (OSA).

### Statistical methods

The analysis aimed to identify the proportion of patients in ambulatory versus non-ambulatory outcome groups as well as perioperative factors associated with non-ambulatory outcomes. A descriptive analysis was conducted of demographic characteristics, co-existing diseases and procedural and postoperative factors. Due to the retrospective nature of the study, an exploratory analysis was conducted within the clinical dataset to identify associations between perioperative factors and non-ambulatory outcomes. Lacking a consistent measurement of perioperative pain, the dosage of fentanyl administered by clinicians managing intraoperative anaesthetics and postoperative pain in the PACU was used as a logical proxy measure of perioperative analgesic requirements. As fentanyl was used consistently for the management of patients’ perioperative pain, the ratio of total PACU fentanyl dosage versus total intraoperative fentanyl dosage was used as a proxy measure of patients’ analgesic requirements. This was computed in the following manner: [(PACU fentanyl dosage, mcg/intraoperative fentanyl dosage, µg) x 100]. Thus, a ratio yielding a percentage of more than 50% would indicate that, of all intraoperative fentanyl administered to a patient, more than 50% of it was administered postoperatively in the PACU.

Both demographic and procedural factors were used to differentiate ambulatory outcomes. Associations with ambulatory outcomes were assessed with analysis of variance for continuous variables and chi-squares for dichotomous variables. Eighteen of the 19 factors listed in Tables 1 and 2 associated with ambulatory outcomes at alpha level of 0.2 were retained for logistical modelling. Body mass index (BMI) was omitted from the modelling, as it was a factor in patient selection for LAGBs. A full stepwise logistic regression modelling of the 18 factors was conducted with a variable retention criterion alpha level of 0.05. Interactions in a saturated nine-variable model were evaluated to illustrate relationships among the model variables.

Given the less-than-optimal nine-variable over-saturated stepwise solution, all 18 factors were remodelled using the best subsets algorithm. Model size selection was based on the evaluation of the change of the best model’s chi-squared statistic relative to the corresponding change in model degrees of freedom. Based on these criteria, our model size was estimated between five and six variables. Comparing these two models, the six-variable model illustrated a marginal improvement in the model chi-squared statistic. Given the low frequency of events modelled and the marginal change in the chi-squared statistic, the five-variable model was retained to assess model fit. A combination of the -2 log likelihood, concordance and C-statistic was used to assess model fit between two five-variable candidate models. These candidate models reflect a one-variable difference from the best six-variable model. The criterion for selection of the best candidate model was a higher -2-log likelihood with a better concordance and higher C-statistic. Model fit was improved by dichotomising the relative change of fentanyl dosage around the overall sample mean through a reduction in model discordance with minimal effect on other fitting parameters.

Interactions within the five-variable model were evaluated by comparing odds ratios across all possible combinations of two-, three-, and four-variable models of the five-variable final model. Odds ratios maintained consistent directionality and magnitude, as they remained inside the 95% confidence interval (CI) of the univariate main effect model for each factor across all models. Thus, the effect of co-linearity does not exist, and there was not a need for any interaction terms. These analyses were conducted with SAS 9.1 software (SAS Institute Inc., Cary, NC, USA). A type I error rate of 5% was used to determine statistical significance.

### Statistical analysis

A classification tree analysis utilising the CART algorithm was used to rank-order the importance of the factors in our descriptive model. This exhaustive search algorithm seeks to produce, from a root node, two child nodes with the least amount of impurity. The impurity function reflects a generalisation of the binomial variance called a Gini index, from which the root node is split into quasi-homogenous child nodes. The exhaustive splitting of child nodes continues until a set stopping criterion based on parent and child node sample size is achieved. Parent node size was limited to 30 patients with a respective child node size of 15 patients. Node splits were regulated by the Gini index with a minimum change in improvement equal to 0.001. The stability of the model was evaluated by a 10-fold cross-validation of the solution. The classification analysis was conducted with IBM SPSS 20 (IBM Corp., Armonk, NY, USA).

### Results

The sample (n=201) was composed predominantly of women (72.6%) with a mean age of 43.4 years (SD=11.4) and a mean BMI of 48.2 (SD=10.3). The mean duration of surgery was 70 minutes. A total of 155 patients (77.1%) received ambulatory LAGB with an average discharge time from the PACU of 2 h. Of those in the non-ambulatory group (n=46; 22.9%), 36 had a 23-hour stay and 10 patients required a 1-2 day hospital admission. Seventy-two patients (35.8%) received a dose of metoprolol. Explicit indications for non-ambulato-
ry LAGB (n=20) were as follows: (i) intraoperative surgical complications (n=4), (ii) severe abdominal pain (n=4), (iii) respiratory distress (n=3), (iv) chest pain (n=2), (v) hemodynamic issues (n=2), (vi) concomitant surgery (n=2), (vii) suboptimal glucose control (n=1), (viii) lethargy (n=1) and (ix) voiding problems (n=1). The remainder of the non-ambulatory patients (n=26) had a 23-hour hospital stay due to combination of complaints of moderate incisional pain and
Table 3. Descriptive model of non-ambulatory LAGB patients

<table>
<thead>
<tr>
<th>Perioperative factors</th>
<th>Adj. Odds Ratio</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyslipidaemia vs. no dyslipidaemia</td>
<td>2.8</td>
<td>1.3-6.2</td>
<td>0.01</td>
</tr>
<tr>
<td>Cardiac arrhythmias vs. no cardiac arrhythmias</td>
<td>21.8</td>
<td>2.9-161.5</td>
<td>0.003</td>
</tr>
<tr>
<td>Increasing number of surgical ports by 1 port</td>
<td>2.2</td>
<td>1.2-4.0</td>
<td>0.007</td>
</tr>
<tr>
<td>PACU fentanyl dosage ratio of ≥ 50%</td>
<td>2.9</td>
<td>1.3-6.2</td>
<td>0.007</td>
</tr>
<tr>
<td>No prophylactic metoprolol vs. prophylactic metoprolol</td>
<td>4.7</td>
<td>1.9-11.9</td>
<td>0.001</td>
</tr>
</tbody>
</table>

PACU: post-anaesthesia care unit; LAGB: laparoscopic-adjustable gastric banding

Both the overall and 10-fold cross-validation risk estimate was 0.274 (std error=0.30) when evaluating the descriptive model of non-ambulatory patients with a classification tree. This suggests that the decision rules governing the tree correctly classified 72.6% of cases, with a relatively stable tree structure evident by the lack of deviation in the overall and cross-validated risk estimate. Thereby, the CRT model calculated a sensitivity of 89.0%, specificity of 56.1% and predictive rate of 64.0%. The number of surgical ports was the strongest predictor of non-ambulatory status (Figure 1) upon review of the order of importance among the model variables based on improvement of the Gini index. Both preoperative metoprolol administration and a ratio of ≥50% of PACU versus intraoperative fentanyl dosage had much less differentiation in their respective predictive strength. Dyslipidaemia and cardiac arrhythmias failed to meet the minimal requirements and augment the likelihood of an ambulatory LAGB outcome.

Discussion

The majority of patients can safely receive an ambulatory LAGB. Additionally, there are significant associations between surgical and anaesthetic perioperative factors and non-ambulatory/ambulatory outcomes. The increase in the number of laparoscopic access ports was the major factor associated with non-ambulatory outcomes. The addition of a single port roughly doubled the risk of a non-ambulatory LAGBs. While the interpretation of the association between the number of laparoscopic ports and PACU recovery characteristics of ambulatory outcomes is beyond the scope of this study, future studies should evaluate and explore these findings and their impact on ambulatory and non-ambulatory outcomes in a randomised trial. The failure of timely and effective postoperative pain control is a major contributing factor for prolonged recovery, unanticipated hospital admissions and re-admissions (12, 13). Thus, it is possible that patients with fewer laparoscopic ports may be more likely to have an ambulatory LAGB outcome. Additionally, utilisation of multimodal analgesia, a proven strategy that minimises postoperative opioid consumption, may help reduce opioid requirements and augment the likelihood of an ambulatory LAGB outcome (13).
A lack of administration of a preoperative dose of metoprolol to patients aged 40 years or older with no medical contraindications significantly increased the risk of a non-ambulatory LAGB outcome. Additionally, a higher ratio of fentanyl administered postoperatively in the PACU (≥50%) was associated with an increased risk of a non-ambulatory outcome after LAGB. A possible explanation for this may be reduced analgesic and anaesthetic requirements associated with perioperative beta-blockade (14, 15). The POISE trial demonstrated more harm than benefit from liberal perioperative administration of beta-blockers to patients having or being at risk of atherosclerotic disease (16). An important distinction between this study and the POISE trial is that just a single metoprolol dose was administered to patients in this study, whereas beta-blockade in the POISE trial was very extensive, starting preoperatively and continuing for 30 days postoperatively. Thus, the most optimal perioperative beta-blockade protocol is yet to be determined.

Postoperative respiratory safety of patients with OSA has been a focus of researchers, hospitals and various organisations. The 2006 American Society of Anesthesiologists practice guidelines for perioperative management of patients with OSA were developed with the aim to help practitioners make rational decisions and provide optimal perioperative care to those patients (17). However, some practitioners do not consider appropriately treated as a contraindication for ambulatory LAGB (6, 18). Such an approach is actually supported by this study that demonstrated similarities in non-ambulatory (39.1%) and ambulatory outcomes (37.4%) of patients with OSA (p=0.83). There was no association between higher BMI and non-ambulatory LAGB outcomes. This finding is supported by similar findings of Cobourn et al. in a series of 1,641 patients (18).

The success of ambulatory LAGB has been linked to the experience of surgeons and anaesthesiologists (2, 6). Skilled surgeons require roughly 1 h of operative time for completion of LAGB (8, 18). Reported conversion rates to an open procedure have ranged from 0% in private practice settings to 8% at academic institutions where residents are involved (6, 7). A mean surgical time of 70 min with no conversions to an open procedure in the current study points towards a reliable surgical technique. In addition, the rate of ambulatory LAGB of 77.1% was within the already reported range of 75%-82.7% (7, 9).

Two patients required a third laryngoscopy and the use of the Eschmann tube introducer for the completion of tracheal intubation. This outcome is in agreement with the finding of Brodsky et al. (19) where the rate of problematic tracheal intubation in the morbidly obese was 1%. Nausea and vomiting are well-known postoperative problems that can cause delayed recovery and unanticipated hospital admission. Prophylactic administration of two commonly used antiemetic drugs was effective in preventing postoperative nausea and vomiting as a cause of hospital admission in the current study. The most important limitations are the retrospective nature of the study and small sample size. Our model is only descriptive of LAGB patients at a single institution. We also recognise that the precision of some of the odds estimates is less than optimal, e.g. a large CI on one variable due to limited events. However, factors deemed clinically relevant were included while maintaining parsimony in the model. Having a single surgeon perform all cases may not be the optimal representation of the population of bariatric surgeons and different outcomes related to various surgical techniques. On the other hand, a single surgeon allowed for continuity of the operative technique, with the surgeon regularly following his or her preoperative medication protocol. Multiple anaesthesiologists involved have used sevoflurane, desflurane and isoflurane for maintenance of anaesthesia based on their personal preferences. However, fentanyl was the primary intraoperative and postoperative analgesic. This allowed continuity of perioperative pain management, an important study outcome. Another limitation relates to the analysis of co-existing diseases. A small sample size of patients with severe co-morbidities limited the results and conclusions concerning their impact on the outcome of ambulatory LAGB.

Conclusion

In summary, the majority of patients received ambulatory LAGBs in this series. The major factor associated with non-ambulatory outcome was an increased number of laparoscopic access ports. Administration of ≥50% of a patient's fentanyl to treat postoperative pain in the PACU and a lack of prophylactic perioperative metoprolol administration were also associated with non-ambulatory outcomes. Co-existing OSA was not associated with non-ambulatory LAGB. The exact effect of other co-existing diseases was difficult to quantify. Thus, meticulous laparoscopic surgical technique with the least number of access ports, anaesthetic technique aimed at reduction of postoperative opioid consumption and utilisation of established prophylactic perioperative medical measures are important factors for a successful ambulatory LAGB outcome.

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