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Surgical site infection in bariatric surgery: results of a care bundle.

Infecção de sítio cirúrgico após cirurgia bariátrica: resultados de uma abordagem com pacote de cuidados.

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ABSTRACT

Objective: to present a descriptive analysis of the results of a care bundle applied to obese patients submitted to bariatric surgery, regarding infection control. **Methods:** a care bundle was designed to control surgical site infection (SSI) rates in patients undergoing bariatric surgery. The bundle included smoking cessation, bathing with 4% chlorhexidine two hours before surgery, cefazolin (2g bolus) in anesthetic induction associated with a continuous infusion of the same drug at a dose of 1g over a two-hour period, appropriate trichotomy, glycemic control, supplemental oxygen, normothermia, intraspinal morphine for the relief of pain, and sterile dressing removal 48 hours after surgery. All patients were followed up for 30 days. **Results:** among the 1,596 included patients, 334 (20.9%) underwent open surgery and 1,262 (79.1%) underwent videolaparoscopic surgery. SSI rates were 0.5% in the group submitted to laparoscopic surgery and 3% in the one submitted to open surgery. The overall incidence of SSI was 1%. Intra-abdominal, respiratory tract, and urinary tract infections occurred in 0.9%, 1.1%, and 1.5% of the sample, respectively. Higher body mass index was associated with higher incidence of SSI (p=0.001). Among patients with diabetes, 2.2% developed SSI, while the rate of infection among non-diabetics was only 0.6%. **Conclusion:** the established care bundle, structured by core evidence-based strategies, associated with secondary measures, was able to maintain low SSI rates after bariatric surgery.

Keywords: Surgical Wound Infection. Patient Care Bundles. Infection Control. Bariatric Surgery.

INTRODUCTION

Despite all medical advances in the field of surgery and all the knowledge acquired over the last decades regarding infection control, surgical site infection (SSI) continues to be a subject of great concern in health institutions, and is closely related to increased nosocomial morbimortality[1]. In the U.S., SSI occurs in 2% to 5% of all patients undergoing surgery and is responsible for an increase of seven to ten days in the mean time of postoperative hospitalization, thus leading to an increase in health expenditure[2,3].

Among the various risk factors for the development of SSI, obesity deserves special attention due to its increasing incidence in the world[4]. Thus, it is plausible to infer that surgical procedures performed primarily in obese patients, such as bariatric surgery, should be related to high SSI rates[5]. Data on the incidence of SSI after bariatric surgery vary from 1% to 21.7%, depending on the surgical access performed (laparoscopy or laparotomy)[6].

In view of the best knowledge of risk factors for SSI, several interventions with varying levels of evidence have been introduced in clinical practice with the aim of reducing the incidence of postoperative infection[7]. Care bundles have been implemented to this end and, even literature presenting conflicting data on this topic, their application seems to be a useful strategy to control SSI in the most diverse performed procedures[3]. Data on care bundles related to SSI prevention in bariatric

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surgery are scarce in literature. Thus, the objective of this study was to present a descriptive analysis of the results of a care bundle applied to obese patients submitted to bariatric surgery, regarding infection control.

METHODS

A prospective cohort study performed at Hospital das Clínicas/Federal University of Pernambuco and Real Hospital Português de Beneficência de Pernambuco, from July 2008 to January 2018. The sample consisted of 1,596 patients who underwent bariatric surgery and joined a care bundle to control infection rates.

This study included patients aged 18-65 years, of both genders, with body mass index (BMI) above 35kg/m^2 and a formal indication for bariatric surgery according to the criteria of Brazilian Society of Bariatric and Metabolic Surgery. Patients with community-acquired infections, assessed through anamnesis and physical examination at the time of hospital admission, were excluded from the study, as well as those who reported infectious events within 30 days prior to surgery.

In the preoperative period, about two hours before surgery, all patients underwent a 4% chlorhexidine soap solution bath. Depilation before hospitalization was completely prohibited and appropriate trichotomy was performed shortly before the surgical incision. Smoking cessation was recommended for the 30 days prior to surgery. Hemoglucotest (HGT) was performed every six hours and the glycemic target was established as values below 200mg/dl. All patients had their glycemia levels controlled below 200mg/dl according to HGT during surgery and up to 48 hours later. Body temperature was strictly controlled, aiming to maintain normothermia throughout surgery and in the immediate postoperative period. In anesthetic induction, all patients received cefazolin (2g bolus) associated with a continuous infusion of the same drug at a dose of 1g over a two-hour period as antibiotic prophylaxis. Sterile dressings were removed within the first 48 hours postoperatively. Intraspinal morphine was administered in anesthetic induction. All patients received supplemental oxygen during surgery and in the post-anesthetic recovery room. All these interventions present in the care bundle used in this study are summarized below: smoking cessation within 30 days prior to surgery; preoperative bath with 4% chlorhexidine two hours before surgery; cefazolin (2g bolus) + 1g in continuous infusion for two hours; appropriate trichotomy shortly before the surgical incision; glycemic control (below 200mg/dl during surgery and up to 48 hours later); supplemental oxygen; intraoperative normothermia and in the immediate postoperative period; intraspinal morphine for postoperative pain control; sterile dressing removal within 48 hours after surgery.

Appropriate trichotomy was defined as the hair removal only when strictly necessary, according to the judgment of the surgeon, and restricted to the operating room under aseptic conditions, shortly before surgical incision.

All included patients adhered 100% to the care bundle presented to them.

In addition to the interventions mentioned above, it was highly recommended to all patients a 10% loss of their weight before surgery.

The main variables studied were: occurrence of superficial SSI (referred here only as SSI), BMI, type 2 diabetes *mellitus* (DM2), and surgical access (open or laparoscopic).

All patients underwent SSI screening in the first 30 days postoperatively. In those cases where signs of SSI were evidenced, the surgeon proceeded with conservative measures to treat the infection, including drainage and saline wound cleaning and, if necessary, antibiotic therapy.

A spreadsheet was created in Microsoft Excel and exported to SPSS software (version 18) for data analysis. Then, percentage frequencies of the variables were calculated, and the frequency distributions were determined. K-S test was applied to evaluate the normality of the distribution. In those cases where normality was confirmed, Student's t-test for paired samples was applied in order to compare the variables between the cases in which there was and there was not SSI. If the normality hypothesis were rejected, Wilcoxon test would be applied. All conclusions were made taking into account a significance level of 95% (p-value <0.05).

The study was approved by the Research Ethics Committee of Federal University of Pernambuco (CEP/CCS/UFPE), according to Resolution nº 196/96 of the National Health Council, under CAAE: 52448616.0.0000.5208.

RESULTS

This study had the participation of 1,596 patients with formal indication for bariatric surgery. Surgeries were performed by laparotomy (20.9%) and by laparoscopy (79.1%). In the preoperative period, 25.9% of the patients presented DM2; 30.9% presented BMI between 35 and 39.9 kg/m^2; 58.9%, between 40 and 49.9 kg/m^2, and 10.2%, above 50kg/m^2. Complications such as SSI and seroma occurred in 16 (1%) and 231 (14.5%) patients, respectively. Intra-abdominal infection was evidenced in 0.9% of the patients (Table 1).

Table 1. *Sample distribution according to the studied variables.*

Variable	n	%
Total	1,596	100.0
Surgery		
Open	334	20.9
Laparoscopy	1,262	79.1
DM2		
Yes	414	25.9
No	1,182	74.1
BMI		
35-39.9kg/m^2	493	30.9
40-49.9kg/m^2	940	58.9
>50kg/m^2	163	10.2
SSI		
Yes	16	1.0
No	1,580	99.0
Seroma		
Yes	231	14.5
No	1,365	85.5
Intra-abdominal infection		
Yes	15	0.9
No	1,581	99.1

BMI: body mass index;DM2: type 2 diabetes mellitus; SSI: surgical site infection.

Table 2 correlates the occurrence of SSI with the other variables studied in this work. The increase in BMI was related to a higher incidence of SSI. Only 0.4% of the patients with BMI between 35 and 39.9 kg/m^2 developed SSI while this index was of 3.7% in those with BMI>50kg/m^2. Among those with BMI between 40 and 49.9 kg/m^2, 0.8% presented SSI (p<0.05).

Table 2. *Correlation between the occurrence of surgical site infection (SSI) and the other studied variables.*

	Surgical site infection		
Variable (n)	Yes	No	p
BMI			
35-39.9kg/m^2 (493)	2 (0.4%)	491 (99.6%)	
40-49.9 kg/m^2 (940)	8 (0.8%)	932 (99.2%)	0.001
>50kg/m^2 (163)	6 (3.7%)	157 (96.3%)	
DM2			
Yes (414)	9 (2.2%)	405 (97.8%)	0.005
No (1182)	7 (0.6%)	1,175 (99.4%)	
Surgery			
Open (334)	10 (3%)	324 (97%)	<0.001
Laparoscopy (1,262)	6 (0.5%)	1,256 (99.5%)	

BMI: body mass index; DM2: type 2 diabetes mellitus.

The presence of DM2 was also related to higher incidence of SSI. Among patients diagnosed with T2DM, 2.2% developed SSI, while only 0.6% of those without DM2 presented this condition, being this difference statistically significant ($p<0.05$).

The surgical approach also showed relationship with SSI rates. Patients operated by laparoscopic access had SSI rates of only 0.5%, while the ones operated by laparotomy showed an incidence of 3% ($p<0.05$).

DISCUSSION

Up to now, there is no literature study reporting the impact of care bundle interventions on obese patients undergoing bariatric surgery. Currently, there are several types of surgical care bundles reported in literature. However, these studies have presented varying numbers of interventions and different levels of evidence. The success of an approach using care bundles does not depend on isolated interventions. The systematic implementation of the care bundle designates the ideal surgical treatment[7,8].

Koek *et al*.[8] have carried out a study analyzing the impact of a national care bundle implementation on the reduction of SSI rates. Their care bundle has been composed of four elements: antibiotic prophylaxis, lack of hair removal, perioperative normothermia, and strict control of door openings in the operating room. They have found that full compliance with the entire bundle has led to a reduction in SSI risk, ranging from 14% to 37% when compared to other compliance levels.

Tanner *et al*.[7] have published a meta-analysis on the effectiveness of the care bundle in reducing the risk of SSI in patients undergoing colorectal surgery. However, they have stated that selective core elements with high levels of evidence, such as glycemic control, normothermia, appropriate trichotomy, and antibiotic prophylaxis, have not been sufficient to reduce the overall risk of infection among these patients.

The care bundle proposed in the present study comprised five evidence-based core interventions - smoking cessation, normothermia, glycemic control, appropriate trichotomy, and antibiotic prophylaxis

selection - besides four additional measures, including preoperative chlorhexidine bath, use of supplemental oxygen, administration of intraspinal morphine, and sterile dressing removal within 48 hours.

Currently, there are well-established evidences in literature regarding smoking and the increased risk of developing SSI. Smoking cessation in the preoperative period leads to lower incidences of SSI[9]. In their study, Nolan *et al*.[10] have found that smoking, on the day of elective surgery, is responsible for a nearly twofold increase in the risk of SSI. Due to the lack of knowledge about the ideal timing of preoperative smoking cessation, the bundle designed in the present study included a recommendation for smoking cessation in the last 30 days prior to hospital admission.

Preoperative antiseptic bath has shown encouraging results in a limited number of studies, including orthopedic, gynecological, and cardiothoracic surgeries[11-14]. Currently, literature is conflicting and there is no consensus on the efficacy of preoperative chlorhexidine bath in abdominal surgeries[15]. A systematic review published on Cochrane Database of Systematic Reviews has shown that there is no clear positive or negative evidence regarding the effectiveness of the preoperative bath or the chlorhexidine bath[12]. Despite the lack of evidence in literature, the use of chlorhexidine in preoperative baths has been incorporated into several protocols because of its proven ability to achieve excellent skin bacterial decolonization[15]. These conflicting results may be due to an absence of standardization in the applying method of the tests[9]. The present study implemented a 4% chlorhexidine gluconate detergent solution whole body bath two hours before surgical procedure.

For antibiotic prophylaxis, first-generation cephalosporins have been widely used, especially in gastrointestinal surgeries, presenting high degree of evidence in literature. Specifically for bariatric surgery, cefazolin seems to be the most widely used antibiotic prophylaxis agent, being presented in the vast majority of published studies[6]. Some studies have evaluated the efficacy of other drugs, such as ertapenem and ampicillin-sulbactam, but they present lower results when compared to cefazolin[16]. Many studies advocate the administration of antibiotic prophylaxis prior to surgical incision[17]. However, other parameters, such as initial dose, need for subsequent doses, and prophylaxis duration, remain varied among preoperative care protocols[6,16]. To provide optimal surgical care in terms of reducing the risk of SSI, it is of utmost importance to understand the pharmacokinetics of the drug chosen and the microbiota involved[16,17]. Alincoara *et al*.[18] have evaluated the pharmacokinetics of cefazolin in obese patients undergoing bariatric surgery. It has been shown that cefazolin (2g bolus) in anesthetic induction, associated with a continuous infusion of the same drug at a dose of 1g for two hours during the surgical procedure, has been able to provide a concentration in the adipose tissue that has remained above the minimum inhibitory concentration throughout the surgical procedure.

The present study included the same antibiotic prophylaxis used and advocated by Alincoara.

In addition, factors such as hyperglycemia and hypothermia during the surgical procedure have been associated with a higher incidence of SSI. Thus, glycemic control and normothermia are widely adopted as measures to avoid SSI[19]. Regarding glycemic control, there are clear evidences that the maintenance of glycemic rates at levels close to the normal established values is an effective practice of infection control. However, it is still controversial how close to normal these levels should be maintained[20,21]. On the other hand, the evidences which support the maintenance of intraoperative normothermia are modest and there is no proven benefit of this practice in gastrointestinal surgeries[22].

Freeman *et al*.[5] have conducted a prospective multicenter cohort study to assess SSI rates after bariatric surgery. They have found a 1.6% SSI rate among laparoscopically operated patients. In their retrospective study, Husain *et al*.[23] have found a 2.1% SSI rate in laparoscopic bariatric surgery and a 20.8% SSI rate in bariatric surgery by laparotomy.

The current study, with the application of our care bundle, found an overall SSI rate of 1%. SSI occurred in only 0.6% of patients undergoing laparoscopic bariatric surgery and in 3% of those undergoing laparotomy. In addition, it was possible to observe that the increase in BMI and the presence of DM2 were responsible for a higher incidence of SSI, in agreement with current literature.

As written before, there are several differences between one bundle and another, with several combinations of different interventions. However, it is important to emphasize that what should be sought is the systematic implementation of the whole care bundle rather than partial compliance with only some bundle interventions. In fact, the complete compliance of the care bundle among the multidisciplinary team is what leads to better surgical care[7,8].

Currently, there is no consensus on what the optimal care bundle in bariatric surgical treatment is. However, this study showed that a multidisciplinary approach, using selective core and evidence-based strategies along with adjunctive interventions, resulted in low rates of surgical infection following bariatric surgery.

R E S U M O

Objetivo: *apresentar uma análise descritiva dos resultados de um pacote de cuidados aplicado em pacientes obesos submetidos à cirurgia bariátrica, no que diz respeito ao controle de infecção.* **Métodos:** *um pacote de cuidados foi estruturado, visando a conter as taxas de infecção de sítio cirúrgico (ISC) em pacientes submetidos à cirurgia bariátrica. O pacote incluiu interrupção de tabagismo, banho com clorexidina 4% duas horas antes da cirurgia, cefazolina 2g em bolus na indução anestésica associada à administração da mesma droga com dose de 1g em infusão contínua, tricotomia apropriada, controle glicêmico, oxigênio suplementar, normotermia, controle da dor com morfina intrarraquidiana e remoção do curativo estéril 48 horas após a cirurgia. Todos os pacientes foram seguidos por 30 dias.* **Resultados:** *entre os 1.596 pacientes incluídos, 334 (20,9%) foram submetidos à cirurgia aberta e 1.262 (79,1%) à cirurgia videolaparoscópica. As taxas de ISC foram de 0,5% no grupo submetido à cirurgia laparoscópica e de 3% nos submetidos à cirurgia aberta. A incidência geral de ISC foi de 1%. Infecções intra-abdominal, do trato respiratório e do trato urinário ocorreram em 0,9%, 1,1% e 1,5% da amostra, respectivamente. Faixas mais elevadas de índice de massa corporal foram associadas a maiores incidências de ISC (p=0,001). Entre os pacientes com diabetes, 2,2% desenvolveram ISC, enquanto a taxa de infecção entre os não diabéticos foi de apenas 0,6%.* **Conclusão:** *o pacote de cuidados instituído, estruturado por estratégias centrais baseadas em evidências, associadas à medidas secundárias, foi capaz de manter baixas taxas de ISC após cirurgia bariátrica.*

Descritores: *Infecção da Ferida Cirúrgica. Pacotes de Assistência ao Paciente. Controle de Infecções. Cirurgia Bariátrica.*

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