The gentamicin–collagen sponge for surgical site infection prophylaxis in colorectal surgery:
a prospective case-matched study of 606 cases

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Short running head: Postoperative surgical site infection

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ABSTRACT

Purpose: Surgical site infection (SSI) is a major concern in CRS. It accounts for 60% of all postoperative complications and has an incidence of between 10% and 30%. The GCS was developed to help avoid SSI. The aim of this study was the evaluation of the efficacy of a gentamicin-collagen sponge (GCS) in preventing SSI after colorectal surgery (CRS).

Method: This study was a retrospective analysis of data collected in a prospective database. 606 CRS patients were enrolled in the study and prospectively assigned to one of two groups. From January 2007 to December 2008, all procedures were performed without the use of GCS (forming the non-GCS group). From January 2009 to July 2011, all procedures included a GCS (forming the GCS group). The primary endpoint was the presence or absence of SSI at postoperative day 30.

Results: The incidence of SSI was 29.7% and 20.8% in the non-GCS and GCS groups, respectively ($p=0.019$). By using a stepwise logistic regression, the predictors of SSI were found to be ASA grade ($p<0.001$), operating time (log-transformed value, $p<0.001$), gender ($p=0.021$) and GCS use ($p<0.001$). By adjusting on these variables, a mean reduction in postoperative hospitalization of 8.3 days was found in the GCS group. The proportions of Clavien IIIB to V were 16.6% and 8.9% for the non-GCS and GCS groups, respectively ($p=0.041$).

Conclusions: This study provides additional evidence of the efficacy of the GCS in reducing SSI rates and shortening hospitalization after CRS.

Keywords

Colorectal surgery

Surgical site infection

Gentamicin collagen sponge

NNIS index

INTRODUCTION

Postoperative surgical site infection (SSI) constitutes a major concern in colorectal surgery (CRS). It accounts for 60% of all postoperative complications and has an incidence of between 10% and 30% [1-3]. Surgical site infections increase morbidity, length of hospitalization and cost and may necessitate invasive endoscopic or surgical procedures. It has been suggested that some non-pharmacological treatments can reduce the incidence of SSI: skin preparation, mechanical bowel preparation, wound protectors, hyperoxia and warming [4-6]. The gentamicin collagen sponge (GCS) was developed to avoid wound infections by providing high local gentamicin concentrations but not the high systemic concentrations associated with nephrotoxicity [4]. The sponge's collagen matrix is biodegradable and can be inserted as an inlay or in the organ space. The GCS was first approved in Germany in 1985 and is currently used in over 60 countries. The GCS's efficacy and safety in digestive surgery have been assessed in several controlled studies. A literature review [7], four randomized, controlled trials (RCTs) [8-11] and a prospective, non-randomized study [12] all concluded that use of a GCS reduced the incidence of SSI. In view of these results, our university medical center started to use GCSs in early 2009. More recently, an RCT [5] with a large patient population (n=602) contradicted the literature results by evidencing a higher SSI rate in a group of patients having received a GCS during digestive surgery. Given these contrasting findings and with a view to taking a definitive decision on GCS use in our institution, we decided to contribute additional, center-specific data concerning the efficacy of the GCS by comparing a historical, non-GCS cohort of patients with a prospective, GCS cohort on the basis of the same, prospective database dedicated to SSI surveillance.

PATIENTS AND METHODS

Trial design

Between January 2007 and July 2011, 606 patients underwent colorectal surgery in the Department of Digestive Surgery at Amiens University Medical Center. All patients were operated on by one of our two colorectal surgeons (OB, AD). In order to assess the value of GCS in preventing post-CRS SSI, we assigned the patients into one of two groups by time period. From January 2007 to December 2008, surgical procedures were performed without a GCS (forming the non-GCS group). From January 2009 to July 2011, a GCS was systematically used (forming the GCS group). Data on the historical control group (non-GCS group) and the treatment group (GCS group) were prospectively collected in an electronic database. There were no significant changes to the surgical and care teams during the overall study period (see the section on peri-operative data collection).

Ethics

The GCS has been approved in France since 2001 and we have used it routinely since January 2009. All patients were informed of the use of GCS before surgical procedure. The study's objectives and procedures were approved by our institution's independent investigational review board as a non-interventional research (CEERNI 42).

Inclusion and exclusion criteria

Included patients were aged 18 or over and had undergone elective or emergency colorectal laparoscopy or laparotomy. We excluded under-18s and patients with aminoside allergy or kidney failure.

Patients

Patients were operated on for colorectal cancer or benign lesions (diverticulitis, inflammatory bowel disease, ischemia and miscellaneous conditions). Colon resection was always performed. Anastomosis or Hartman procedure were performed depending on the type of

surgery, the pathology, local conditions (ie peritonitis) or general conditions. Whenever possible, we performed an anastomosis. Sometimes in cases of peritonitis, preoperative fecal incontinence or cardiovascular collapsus we preferred achieve a stoma without anastomosis. When anastomosis was performed, a diverting stoma was created in some (but not all) cases.

Definitions (Table 1)

Postoperative surgical site infections

We recorded the presence or absence of SSIs occurring within 30 days of the surgical procedure. SSI are usually classified into three categories: [13].

Clavien classification

Postoperative morbidity and mortality were described according to Clavien's classification [14].

The Altemeier classification

The Altemeier classification characterizes surgical wounds. [15].

The NNIS Index

The risk of infection was assessed with the use of the National Nosocomial Infection Surveillance System (NNIS), a composite index that aggregates the Altemeier classification, the American Society of Anesthesiology score (ASA) and the operating time [16].

Surgical procedure

Preoperative work-up was performed according to the current guidelines [17,18]. All patients were admitted on the day before surgery. Colon enema was not performed for colon resection [17]. For rectal resection, the bowel was prepared by administration of oral laxatives and retrograde enemas [18]. Senna solution (X-Prep® from Laboratoires Sarget, Mérignac, France) was provided 24 hours before the operation. Peri-operative, prophylactic antibiotics (500 mg of metronidazole and 1 gram of ceftriaxone in 125 mg of saline solution) were infused intravenously for 15 minutes following the induction of anesthesia. Prophylactic

antibiotics were again infused 30 minutes after skin incision and then every 2 hours during the surgical procedure (in accordance with French national guidelines [19]).

Sponge insertion

Collatamp® sponges (10 cm by 10 cm, from Eusapharma (Limonest, France)) contained 280 mg of collagen and 200 mg of gentamicin sulfate. The implantation of one gentamicin-collagen sponge (corresponding to a gentamicin dose of 130 mg) results in local-tissue gentamicin concentrations of 170 µg per milliliter. Systemic concentrations of gentamicin remained below 2 µg per milliliter 24 hours after implantation [20]. Sponges were placed directly onto the tissue without prior wetting. For procedures with anastomosis and under laparotomy or laparoscopy, a circular peri-anastomotic sponge was inserted after anastomosis creation. For procedures in the absence of anastomosis, Collatamp® sponges were inserted close to a suture (e.g. at the rectal stump). Collatamp® sponges were placed at every time (laparotomy or laparoscopy) around the colorectal anastomosis or around the rectal stump in case of Hartmann procedure. For laparotomy procedures, a sponge was inserted into the abdominal wall.

Peri-operative data collection: SSIs, Clavien grading and follow-up

Since January 2007, we have fully documented each operation in a prospective database (DxCare® from Medasys (Gif-sur-Yvette, France)) by recording preoperative variables (height, weight, BMI, diabetes antecedents, age, gender, ASA score, etiology (cancer, diverticulitis, inflammatory bowel disease or other), emergency or elective surgery), peroperative variables (organ group, operating time, Altemeier classification, type of surgery, presence or absence of anastomosis, presence or absence of a protective stoma), underlying disease (Cancer, diverticulitis, Inflammatory bowel disease) and postoperative variables (medical or surgical complications, SSI occurrence, length of postoperative hospitalization (LPH), NNIS grade and Clavien grade [21]). A total of 606 patients who underwent colorectal

surgery were enrolled in this study. We assigned the patients into two groups by period of time. From January 2007 to December 2008, all procedures were performed without the use of GCS (non-GCS group). From January 2009 to July 2011, all procedures included a GCS (GCS group). Morbidity was documented at the time of occurrence (Clavien I-V) or, in the absence of complications, at discharge (Clavien 0). The SSI data were completed at postoperative day 30. In the event of SSI occurrence before postoperative day 30, the data was completed at the time of occurrence. Standard preoperative demographic and intra-operative characteristics were also recorded. At the time of study, full information on 4990 patients was available. Data were extracted as a Excel® file (Microsoft Corporation, Redmond, WA, USA) by using Business Objects® software (version 12.1.0.882) (SAP France S.A Capital 8 - 32 rue de Monceau 75008 Paris).

Outcome measures

The primary endpoint was the presence or absence of SSI at postoperative day 30. Secondary endpoints were the LPH (in days), and the proportion of patients with severe postoperative outcomes (surgical, endoscopic or radiological re-intervention for SSI or Clavien III to V postoperative day 30 morbidity and mortality).

Data Monitoring Committee

The occurrence and nature of Clavien-graded surgical complications was systematically reviewed and assessed by the study's two lead investigators (OB, JMR). Case report forms were checked for validity. In the event of aberrant findings or mismatch between the two interpretations, the reviewers met and reached a consensus.

Statistical analysis

In this prospective matched-case study, each patient in the GCS group was matched for age, gender, surgery duration, Altemeier classification, ASA score and circumstances with two patients of the control historical non-GCS group (ration 1:2). Matching was organized

following the optimal method [22], discarding control units outside the convex hull of the treated units [23]. The primary analysis was based on an intent to treat principle, in which all the patients sequentially admitted, were included into the analysis, without any possible exclusion. We used a mixed model featuring a logistic regression in using blocks as random factor, matching variables as covariates, other available covariates (BMI, diabetes antecedents, use of anastomosis, underlying disease), and treatment as fixed factor. The proportion of patient experiencing SSI was compared between groups within each NNIS category and age category (Mantel Haenszel test). Time to discharge was compared between the two groups by a linear model using baseline variables. Finally, the proportion of patients with severe outcome (Clavien IIIb-V) was compared in adjusting for age (Mantel-Haenszel test). Under these assumptions, and based on a matching ratio 1:2, a sample size of at least 202 patients treated with GCS was needed to detect a SSI reduction of at least 10% with a power of 90%, at two-sided significance level of 0.95. No formal interim analysis was planned. An independent data and safety monitoring committee monitored the trial. All statistical analyses were performed with the use of R software (version 2.11.1) (Free Software Foundation, Inc. 51 Franklin St, Fifth Floor, Boston, MA 02110-1301 USA).

RESULTS

Patient description and intergroup comparisons

Once 202 patients were available in the GCS group (as planned by the sample size calculation), they were matched with 404 untreated patients (non-GCS group). No patient was lost to follow-up. The sample was constituted by 42% of women and a mean age of 63 years (range 68-79) (**Table 1**). The two groups matched well on all the variables, for matching variables as well as for all the other baseline characteristics (diabetes, pre-operative conditions, underlying disease, BMI, emergency of elective conditions, and underlying

disease).

Incidence of surgical site infection

The incidences of SSI were 29.7% in the non-GCS group and 20.8% in the GCS group, (Odds Ratio OR=0.514, 95%CI 0.306-0.865, $p=0.013$). The comparison of SSI proportion between the two groups within each NNIS category (**Table 2**) provides evidence of a constant relative efficacy of GCS compared with control across the 4 categories of severity (Mantel Hanszel, $p=0.019$). By using a stepwise logistic regression, the predictors of SSI were found to be ASA grade ($p<0.001$), operating time (log-transformed value, $p<0.001$), gender ($p=0.021$) and GCS use ($p<0.001$). After adjusting on these previous variables, all the other variables (anastomosis, BMI, Diabetes duration, emergency or elective conditions of surgery, underlying disease differentiating cancer, diverticulitis, Inflammatory bowel) were not found significantly determinant of SSI. By adjusting on these variables, a mean reduction in postoperative hospitalization of 8.3 days was found in the GCS group. The proportions of Clavien IIIB to V were 16.6% and 8.9% for the non-GCS and GCS groups, respectively ($p=0.041$).

Secondary endpoints

We compared the mean LPH in the two treatment groups by applying a stepwise linear regression model based on baseline covariates (**Table 3**). The mains predictors were operating time (with increase of 1.13 days per additional hour of surgery, 95%CI 0.34-1.91, $p<0.001$), ASA grade (with an increase of 6.69 days per each additional grade 95%CI 4.93-8.45), and gender (with a decrease of 3.15 days for women, 95%CI -5.82, -0.48, $p=0.021$). Finally GCS having the effect of a mean reduction of LPH of 8.3 days [95%CI -11.09, -5.51, $p<0.001$]. When the previous variables were considered in the model The other tested covariates (BMI, diabetes antecedents, underlying disease, type of surgery, anastomosis) were non significant, The proportion of patients with severe outcome (Clavien Grade IIIB-V) was compared

between the two treatments across age categories (**Table 4**). Proportions of 16.6% and 8.9% were found for non-GCS and GCS group, respectively. (Risk Ratio $RR_{\text{Control/Treated}} = 0.58$, 95%CI 0.344 to .097, $p=0.041$). In cases of SSI, a systematical bacteriological examination was performed. There were 3 bacteria in 10% of cases ($n=17$), 2 bacteria in 40% ($n=64$), a single one in 40% ($n=64$) and no bacteria in 10% ($n=17$). The most frequent bacteria were E Coli in 50% ($n=81$), Enterobacter aerogenes in 20% ($n=33$), Enterobacter cloacae in 10% ($n=17$) and Enterococcus spp in 30% ($n=50$).

DISCUSSION

The primary endpoint (SSI at postoperative day 30) was compared between the two groups in estimating the difference of SSI between both groups in stratifying between each category of NNIS. We found a significant higher incidence of SSI in the control non-GCS group than in the GCS group (29.7% vs. 20.8%, respectively). This result is in line with other studies on Collatamp®, with the exception of Bennett-Guerrero et al. [5]. Nowachi et al. found a lower postoperative complication rate in the GCS group; relative to the control group (20.7% vs. 37.5%) [10]. De Bruin et al. found significantly lower wound complication rate (11% vs. 29% in the GCS and non-GCS groups, respectively) [12]. Rutten et al. found lower SSI rate in the GCS group (5.6%, vs. 18.4% in the non-GCS group) [8]. In contrast, Bennett-Guerrero et al. found a higher SSI rate in the GCS group than in the control group. Bennett-Guerrero et al. suggested that the length of follow-up (not mentioned in the other studies) could explain the difference of results between their study and the others. In our study, SSI was evaluated on postoperative day 30. Cases of later complaints by the patient were fully documented in our prospective database [12]. The apparent lack of benefit of a GCS in Bennett-Guerrero et al.'s report may be explained by the inlay location of GCS in their cases (compared with inlay and abdominal cavity sites in our present work). Moreover, Bennett-Guerrero et al. only included

patients with elective procedures, whereas our study featured both emergency and elective CRS. Our results showed that patients in the GCS group were hospitalized for 8 days less than those in the non-GCS group (on average) and thus confirmed the positive effect of Collatamp®. This finding confirms de Bruin et al.'s report of shorter hospitalization in a GCS group (15 days, vs. 25 days in a non-GCS group) and Rutten et al.'s report (13.8 days in a GCS group vs. 16.3 days in a non-GCS group). The shorter stay may be due to a lower SSI rate in GCS-treated patients. In our study we had no group of patients with collagen sponge without gentamicin and collagen is usually not used alone around the anastomoses. Collagen is used for haemostasis in general surgery, in the treatment of the liver cross section following hepatectomy but not for an antiseptic effect [24]. Our study had a number of limitations. It was not an RCT; a consecutive series of patients received standard care but only the last 202 were treated with a GCS. Although this design is known to be less accurate than an RCT, it has been already used in a surgical context [25]. Moreover, the study procedures were designed to minimize sources of bias: (i) before analyzing any other results, we confirmed the absence of trend over time in the SSI rate; (ii) we sequentially treated all the patients, with no exclusions or exceptions and (iii) we controlled for possible baseline discrepancies. Our tests were stratified into baseline severity categories and so the small observed intergroup differences are less likely to have influenced our results.

CONCLUSION

Our study provides additional evidence of the efficacy of GCS in reducing SSI rates and shortening hospitalization after colorectal surgery. In view of the recent conflicting results, further clinical studies are required.

DISCLOSURE STATEMENT

The Association for Research in Surgery, Gastroenterology and Hepatology (Chairperson: JM Regimbeau; Secretary: O. Brehant) has received an unconditioned grant from EUSA Pharma (3 Allée des Sequoias, F-69760 Limonest, France) to conduct the trial. Professor Ph Leheret has received an unconditioned grant from EUSA Pharma to conduct the statistical analysis of this trial. The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The GCS was not provided free of price by the sponsor. No contract of confidentiality or request of the company to review the results was signed. The remaining authors have nothing to declare.

REFERENCES

1. Reid K, Pockney P, Draganic B, et al. (2010) Barrier wound protection decreases surgical site infection in open elective colorectal surgery: a randomized clinical trial. *Dis Colon Rectum* 53:1374-80
2. Astagneau P, Rioux C, Golliot F, et al. INCISO Network Study Group. (2001) Morbidity and mortality associated with surgical site infections: results from the 1997-1999 INCISO surveillance. *J Hosp Infect* 48:267-74
3. Smith RL, Bohl JK, McElearney ST, et al. (2004) Wound infection after elective colorectal resection. *Ann Surg* 239:599-605
4. Murray BW, Huerta S, Dineen S, Anthony T. (2010) Surgical site infection in colorectal surgery: a review of nonpharmacologic tools of prevention. *J Am Coll Surg* 211:812-22
5. Bennett-Guerrero E, Pappas TN, Koltun WA, et al; SWIPE 2 Trial Group. (2010) Gentamicin-collagen sponge for infection prophylaxis in colorectal surgery. *N Engl J Med* 363:1038-49
6. Alexander JW, Solomkin JS, Edwards MJ, et al. (2011) Updated recommendations for control of surgical site infections. *Ann Surg* 253:1082-93
7. De Bruin AFJ, Gosselink MP, van der Harst E, Rutten HJ. (2010) Local application of gentamicin collagen implants in the prophylaxis of surgical site infections following gastrointestinal surgery: a review of clinical experience. *Tech Coloproctol* 14:301-10
8. Rutten HJ, Nijhuis PH. (1997) Prevention of wound infection in elective colorectal surgery by local application of a gentamicin-containing collagen sponge. *Eur J Surg* 578:31-5
9. Musella M, Guido A, Musella S. (2001) Collagen tampons as aminoglycoside carriers to reduce postoperative infection rate in prosthetic repair of groin hernias. *Eur J Surg* 167:130-2
10. Nowacki MP, Rutkowski A, Oledzki J, et al. (2005) Prospective, randomized trial examining the role of gentamycin-containing collagen sponge in the reduction of

postoperative morbidity in rectal cancer patients: early results and surprising outcome at 3-year follow-up. *Int J Colorectal Dis* 20:114-20

11. Yetim I, Ozkan OV, Dervişoglu A, et al. (2010) Effect of local gentamicin application on healing and wound infection in patients with modified radical mastectomy: a prospective randomized study. *J Int Med Res* 38:1442-7

12. de Bruin AF, Gosselink MP, Wijffels NA, et al. (2008) Local gentamicin reduces perineal wound infection after radiotherapy and abdominoperineal resection. *Tech Coloproctol* 12:303-7

13. Horan TC, Gaynes RP, Martone WJ, et al. (1992) CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. *Am J Infect Control* 20:271-4

14. Dindo D, Demartines N, Clavien PA. (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 240:205-13

15. Altemeier WA, Burke JF, Pruitt BA, Sandusky WR. (1976) *Manual on control of infection in surgical patients*. Philadelphia: JB Lippincott

16. Emori TG, Culver DH, Horan TC, et al. (1991) National nosocomial infections surveillance system (NNIS): description of surveillance methods. *Am J Infect Control* 19:19-35

17. Slim K, Vicaut E, Launay-Savary MV, Contant C, Chipponi J. (2009) Updated systematic review and meta-analysis of randomized clinical trials on the role of mechanical bowel preparation before colorectal surgery. *Ann Surg* 249:203-9

18. Bretagnol F, Panis Y, Rullier E, et al. (2010) Rectal cancer surgery with or without bowel preparation: The French GRECCAR III multicenter single-blinded randomized trial. *Ann Surg* 252:863-8

19. Consensus conference. (1993) Antibiotic prophylaxis in surgery in adults. French Society of Anesthesia and Intensive care (11-12 December 1992). *Ann Fr Anesth Reanim* 12:337-54
20. Ruszczak Z, Friess W Collagen as a carrier for on-site delivery of antibacterial drugs. *Adv Drug Deliv Rev.* 2003;55:1679-98
21. Brehant O, Lehert P, Sabbagh C, Dhahri A, Fuks D, Regimbeau JM. (2010) Prospective collection of surgical site infections in digestive surgery: is the NNIS index still relevant? *J Visc Surg* 147:30
22. Ho DE, Imai K, King G, et al. (2011) MatchIt: Nonparametric preprocessing for parametric Causal Inference. *Journal of Statistical Software* 42:1-28
23. King G, Zeng L. (2007) When can History be our guide? The pitfalls of counterfactual inference. *International Studies Quarterly* 51:183-210
24. Schwarz L, Lubrano J, Scotté M. Treatment of the liver cross section following hepatectomy. *J Visc Surg.* 2011;148:336-45
25. Kawai M, Tani M, Terasawa H, et al. (2006) Early removal of prophylactic drains reduces the risk of intra-abdominal infections in patients with pancreatic head resection : prospective study for 104 consecutive patients. *Ann Surg* 244:1-7

Table 1: Definitions of the SSI, Clavien classification and the Altemeier classification:

Surgical site infection	
Superficial SSI	SSI involving only skin and subcutaneous tissue of the incision
Deep SSI	SSI which involves deep soft tissues (whether inlay or underlay)
SSI of organ spaces	SSI of organ spaces opened or handled during surgery

Clavien classification	
Grade I	Any deviation from the normal course after surgery with no need for pharmacological, surgical, endoscopic and radiological interventions
Grade II	Complications requiring pharmacological treatment
Grade III	Complications requiring surgical, endoscopic or radiological intervention
Grade IV	Life-threatening complications requiring intermediate or intensive care unit management
Grade V	Death

Altemeier classification	
1	Clean, ,
2	Clean-contaminated
3	Contaminated or dirty

Table 2. Comparison of the two patient groups (^{p value})

	No GCS		GCS		Total	
Gender ^{0.568}	(404)	42.6%	(202)	40.1%	(606)	41.7%
Age ^{0.085}	64.52	± 16.42	62.11	± 16.32	63.72	± 16.41
Weight ^{0.568}	72.09	± 16.13	73.03	± 15.08	72.31	± 15.88
Height ^{0.332}	1.67	± 0.08	1.68	± 0.09	1.68	± 0.09
BMI ^{0.928}	25.71	± 5.38	25.75	± 4.72	25.72	± 5.23
Surg Duration ^{0.251}	198.24	± 105.23	208.32	± 95.38	201.60	± 102.08
Altmeier^{0.116}						
-Clean	1.2%	5	0.0%	0	0.8%	5
-Clean+contam	59.2%	239	66.8%	135	61.7%	374
-Contaminated	28.7%	116	25.7%	52	27.7%	168
-Dirty	10.9%	44	7.4%	15	9.7%	59
ASA Index^{0.269}						
-Healthy patient	5.2%	21	4.5%	9	5.0%	30
-Mild Disease	42.3%	171	49.0%	99	44.6%	270
-Severe Disease	39.6%	160	38.1%	77	39.1%	237
-Threat for life	12.9%	52	8.4%	17	11.4%	69
NNIS^{0.183}						
-Grade 0	13.9%	56	17.3%	35	15.0%	91
-Grade 1	42.6%	172	44.1%	89	43.1%	261
-Grade 2	31.9%	129	32.2%	65	32.0%	194
-Grade 3	11.6%	47	6.4%	13	9.9%	60
Underlying disease^{0.969}						
-Cancer	48.5%	196	48.6%	67	48.5%	263
-Diverticulitis	32.4%	131	34.1%	47	32.8%	178
-Inflam Bowel	10.1%	41	9.4%	13	10.0%	54
-Other	8.9%	36	8.0%	11	8.7%	47
Anastomosis ^{0.146}	64.3%	260	70.9%	100	66.0%	360
Diabetes ^{0.180}	15.1%	61	10.4%	13	14.0%	74
Emergency Surgeries ^{0.112}	36.6%	148	30.2%	61	34.5%	209

Comparison between treatment groups

NNIS: National Nosocomial Infection System

Table 3. Incidence of SSIs in the two patient groups and for each NNIS subgroup (p=0.019 in a Mantel-Haenszel test)

	No		GCS		Total	
	Count	Percent	Count	Percent	Count	Percent
Grade 0	56	17.9	35	5.7	91	13.2
Grade 1	172	22.7	89	12.4	261	19.2
Grade 2	129	37.2	65	33.8	194	36.1
Grade 3	47	48.9	13	53.8	60	50.0
Total	404	29.7	202	20.8	606	26.7

SSI category by NNIS by Treatment (Count, Percent).

Table 4. Stepwise linear regression on length of postoperative hospitalization

	Coef	95% CI	Pval
Mean Duration	11.658	7.871, 15.445	<.001
Length of postoperative hospitalization	1.128	0.344, 1.913	0.005
ASA score	6.697	4.935, 8.459	<.001
Female Patients	-3.153	-5.823, -0.482	0.021
GCS Effect	-8.302	-11.090, -5.514	<.001

Adjusted R²=0.1418, Altmeier Index, age, circumstances, underlying disease, anastomosis use, BMI, and diabetes antecedents were excluded by stepwise regression. Mean Duration corresponds to mean estimated Hospitalization duration corresponding to Male patients with surgery duration of 2 hours, and ASA=Grade 1.

Table 5. Count and Percentage of patients with Clavien grade IIIb or IV or V in the two treatment groups stratified by age. (Mantel Haenszel test adjusting for age, $p=0.017$).

	No		GCS	
Less 60 years	141	4.3%	77	3.9%
60-80 years	183	20.8%	96	11.5%
More 80 years	80	28.7%	29	13.8%
Total	404	16.6%	202	8.9%

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