Original Article

Comparison of surgical infection rates after implementation of a safety checklist

Comparação das taxas de infecção cirúrgica após implantação do checklist de segurança

Comparación de las tasas de infección quirúrgica luego de implantación del checklist de seguridad

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Keywords
Surgical wound infection; Infection control; Patient safety; Checklist

Descritores
Infecção da ferida cirúrgica; Controle de infecções; Segurança do paciente; Lista de checagem

Descriptores
Infección de la herida quirúrgica; Control de infecciones; Seguridad del paciente; Lista de verificación

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Abstract
Objective: To compare surgical site infection rates in clean surgery before and after implementation of the checklist proposed by the World Health Organization.
Methods: Observational, descriptive, retrospective correlational study performed in a general hospital. Sample consisting of 15,319 records of clean surgeries monitored by the hospital Infection Prevention and Control Service, in the trauma, orthopedics, cardiovascular, plastic, general, and urology specialties. Before implementing the checklist, 5,481 records were evaluated; 9,838 records were reviewed after. Analysis was performed with SPSS 22.0 software and application of the Pearson's chi-square test, considering $p < 0.05$.
Results: The overall infection rate in clean surgery was 4.17% in the pre-implementation period of the checklist and 1.10% post-implementation ($p<0.05$), with statistically significant reductions in spine, aneurysm and bypass, abdominoplasty, mammoplasty, herniorrhaphy and prostatectomy surgeries.
Conclusion: A significant reduction was identified in the rate of surgical site infection in clean surgeries when comparing the pre- and post-implementation periods of the checklist proposed by the World Health Organization.

Resumo
Objetivo: Comparar taxas de infecção de sítio cirúrgico em cirurgia limpa antes e após implantação do *checklist* proposto pela Organização Mundial de Saúde.
Métodos: Estudo observacional, descritivo, retrospectivo do tipo correlacional, realizado em um hospital geral. Amostra constituída por 15.319 registros de cirurgias limpas das especialidades traumato-ortopedia, cardiovascular, plástica, geral e urologia monitoradas pelo Serviço de Controle de Infecção Hospitalar. Antes da implantação do *checklist* foram avaliados 5.481 registros e após 9.838. Análise realizada com Software SPSS 22.0 e aplicação do teste qui-quadrado de Pearson, considerando-se significativo $p<0,05$.
Resultados: A taxa geral de infecção em cirurgia limpa foi 4.17% no período pré-implantação do *checklist* e 1.10% pós ($p<0.05$), com redução estatisticamente significativa nas cirurgias de coluna, aneurisma e *by-pass*, abdominoplastia, mamoplastia, herniorrafia e prostatectomia.
Conclusão: Observou-se redução significativa da taxa de infecção de sítio cirúrgico nas cirurgias limpas quando comparados os períodos pré e pós-implantação do *checklist* proposto pela Organização Mundial de Saúde.

Resumen
Objetivo: Comparar tasas de infección de sitio quirúrgico en cirugía limpia antes y después de implantación del *checklist* propuesto por Organización Mundial de la Salud.
Métodos: Estudio observacional, descriptivo, retrospectivo, tipo correlacional, realizado en hospital general. Muestra de 15.319 registros de cirugías limpias de traumatología-ortopedia, cardiovascular, plástica, general y urología, monitoreadas por Servicio de Control de Infección Hospitalaria. Antes de implantarse el checklist fueron evaluados 5.481 registros, y 9.838 después. Análisis realizado aplicando Software SPSS 22.0 y test de Chi-cuadrado, considerándose significatividad de $p<0,05$.
Resultados: La tasa general de infección en cirugía limpia fue 4,17% en período preimplantación del checklist, y 1,10% en el posterior ($p<0,05$), con reducción estadísticamente significativa en cirugías de columna, aneurismas y by-pass, abdominoplastía, mamoplastía, herniorrafia y prostatectomía.
Conclusión: Observada significativa reducción de tasa de infección del sitio quirúrgico en cirugías limpias al compararse períodos pre y post implantación del *checklist* propuesto por la OMS.

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Introduction

Healthcare-associated infections (HAIs) are recognized worldwide as a serious public health problem, as the most frequent adverse events related to patient care, and they are associated with high morbidity and mortality, and increased length of stay and hospital costs.[1,2]

Among the HAIs, surgical site infection (SSI) has a prominent role, which can be manifested up to 30 days after surgery, or up to 90 days after if an implant is used, and are classified according to the degree of involvement, namely: superficial incision, deep incision, or organ and/or space infection.[3,4]

Surgical site infection is one of the main targets of epidemiological surveillance in health institutions. In underdeveloped and developing countries, it is estimated that SSI can affect up to one-third of patients undergoing surgical procedures and, although less frequent in industrialized countries, it is the second among the HAIs in Europe and the United States.[2,5] Surgical site infection is one of the major risks related to patient safety in the health services of Brazil and, among all the HAIs, it occupies the third position, comprising 14 to 16% of those infections identified in hospitalized patients.[1,4]

Each SSI episode prolongs the mean time of hospitalization by 7 - 11 days; the mortality risk is 2 - 11 times greater when comparing patients with and without infection; the cost is extremely onerous, varying according to the type of procedure; and,[5,6] has a negative impact in the quality of life of the patients and on the institution's image.[5,6] Approximately 50 - 60% of SSI are preventable by means of evidence-based strategies.[3]

Surgeries are classified as, according to the potential for contamination of the site handled: clean, potentially contaminated, contaminated, and infected wounds.[4] Clean wound surgeries are those performed on sterile or decontaminated tissue in the absence of local infectious and inflammatory processes or gross technical failures; elective and traumatic surgeries with first intention healing and without drainage; or surgeries in which no penetration of the digestive, respiratory or urinary tract occurs.[3] These are the recommended and prioritized procedures for surgical surveillance, and, in general, the acceptable SSI rates range from 1 - 5%. The monitoring of this indicator enables an indirect evaluation of items potentially related to the infection.

Minimizing the risk of infection and perioperative complications became a global priority of the patient safety movement when the World Health Organization (WHO) defined the surgical care theme of the second global challenge, entitled "Safe Surgeries Saves Lives",[7] as part of the World Alliance for Patient Safety.[8]

The challenge aims to improve safety by adopting a tool, designed to be practical and easy for professionals interested in reducing the number of deaths and unnecessary injury to apply. This is a surgical checklist of items to be reviewed by the professionals at three different moments within the surgical procedure: before anesthetic induction, before the surgical incision, and before the patient leaves the operating room. Among the 19 items to be checked, two are directly related to SSI prevention: administration of surgical antibiotic prophylaxis (prior to skin incision), and sterilization of the materials/equipment to be used in the surgical procedure.[7] Implementation requires the involvement and support of organizations, resulting in improved quality of care processes based on the reduction of morbidity and mortality, improvement of communication and teamwork, optimization of surgical time, and reduction of costs.[9-11]

As a WHO member country, Brazil joined the Global Alliance for Patient Safety and recommended, by means of Ministerial Resolution RDC No. 36,[12] the implementation of strategies for patient safety. Among these was the Guideline for Safe Surgery in health facilities, which includes administration of a checklist.

Some studies have been published in recent years,[10,13] reporting the implementation of this global challenge and the impact on the reduction of complications, adverse events and mortality related to surgical care. Studies[14-16] performed in Brazil are predominantly experience reports of implementation, and assessment of adherence to the checklist;

studies that demonstrated effectiveness in clinical outcomes with the implementation of this global challenge are limited.

With the goal to conduct a study that evaluates the results of administration of the checklist in the Brazilian scenario, the problem to investigate was: is the incidence of SSI different in clean surgeries before and after the implementation of the checklist? Thus, the aim of the study was to compare the rates of surgical site infection in clean surgery before and after the implementation of the checklist proposed by the World Health Organization.

Methods

This was an observational, descriptive, retrospective, and correlational study comparing the SSI rate of clean surgeries before and after the implementation of the surgical safety checklist proposed by the WHO.[17]

The field of action was a large private general hospital located in Rio Grande do Sul, Brazil. The study was conducted in twelve operating rooms, which annually perform approximately 16,000 surgical procedures from low to high complexity, in the most diverse specialties, except for transplants.

The sample was intentional and consisted of 15,319 clean surgeries monitored by the hospital Infection Prevention and Control Service (IPCS). Annually, this service monitors approximately 2,600 surgeries of the general specialties, urology, cardiac, neurosurgery, thoracic, vascular, plastic and trauma-orthopedics; approximately 80% of these procedures are clean surgeries. The inclusion criteria were all the procedures monitored throughout the study period, excluding neurosurgery and thoracic surgery procedures, because IPCS started monitoring these procedures only in 2010.

The period before the implementation of the checklist used in the study was from January 1, 2006 to December 31, 2009; 5,481 procedures were analyzed. After implementation, the period studied was from January 1, 2011 to December 31, 2014; 9,838 procedures were analyzed. Data from the year 2010 was excluded because this was considered to be the year of implementation of the checklist in the institution, which occurred gradually over the 12 months, according to the plan established by the hospital.

The surgical safety checklist implemented was faithful to the one proposed by the WHO, where safety items are checked at three different moments: before induction of anesthesia, before the skin incision, and before the patient leaves the operating room. Of the 19 items checked, two of them were directly related to SSI prevention, and were checked prior to the skin incision, namely: review of materials sterilization by the nursing team, and antimicrobial prophylaxis 60 minutes before the skin incision.[7] In the hospital where the study was conducted, the circulating nursing technician in the operating room has the responsibility of checking the items with the teams involved in the surgical procedure, and the operating room nurse is accountable for supervision and orientation during the process.

Secondary data were obtained from the IPCS database. The epidemiological surveillance methodology used by this service was the active surveillance for SSI, which consists of daily follow-up of the patients, with analysis of the medical records during the hospitalization period, searching for clues for SSI diagnosis (fever, antimicrobial use, exudation, positive cultures, in addition to laboratory and radiological exams) and post-discharge surveillance, by telephone contact or e-mail with the surgical teams within 30 days after discharge, looking for occurrence of infection in patients. The diagnostic criteria for classification of infection follow the one established by the National Health Surveillance Agency (Agencia Nacional de vigilância Sanitária) - ANVISA.[4]

The SPSS software version 22.0 was used for statistical analysis. Categorical variables were described in frequency and proportions, infection rates per patient and procedure. For comparison, the Pearson chi-square test was used, considering values to be statistically significant when $p < 0.05$.

The study was approved by the Research Ethics Committee of the institution with protocol No. CAAE 32829814.5.0000.5304, and the institu-

tion's consent was obtained for using information from the IPCS database.

Results

During the study period, 131,053 surgeries were performed, with a wide range of specialties and the extent of the surgery. Of these, 26,225 (20.0%) were monitored by IPCS, and 20,373 (77.7%) corresponded to clean surgeries as demonstrated in table 1.

In the pre-intervention period (2006-2009), 5,481 clean surgeries were included and in the post-period (2011-2014) were 9,838 procedures. The SSI rate in clean surgery was 4.17% and 1.10%, respectively (p <0.05), with an RR of 0.25 (0.20-0.32).

Table 1. Surgical procedures performed annually at the institution, and procedures monitored by the Hospital Infection Prevention and Control Service

Year	Surgeries performed in the institution n	Surgeries monitored by the IPCS	
		Total n	Clean surgery n
2006	11,909	2,114	1,230
2007	13,730	2,305	1,312
2008	13,972	3,421	2,084
2009	14,323	2,204	982
2010	15,082	2,713	2,528
2011	14,971	3,968	3,739
2012	16,561	3,814	3,559
2013	15,190	3,122	2,729
2014	15,315	2,564	2,210
Total	131,053	26,225	20,373

Infection Prevention and Control Service (IPCS)

The stratification by surgical specialties, comparing the pre- and post-implementation period of the surgical safety checklist is presented in figure 1.

In the period prior to the implementation of the checklist, 1,463 surgeries from the prosthetic-orthopedic specialty were analyzed, with 4.85% SSI, and in the post-implementation, among the 2,353 procedures, 2.43% SSI (p<0.001). In the cardiovascular procedures, 528 pre-implementation and 666 post-implementation procedures were evaluated, and the SSI rate was, 7.01% and 3.30%, respectively (p<0.003). In aesthetic plastic surgery, the number of surgeries was 1,759 and the SSI rate was 1.02% in the pre-implementation period, and there were 4,731 post- implementation procedures with a SSI rate of 0.06% (p<0.001).

The stratification by surgical procedure (Table 2), showed a statistically significant reduction in the SSI rate in spinal (5.91 x 2.43), aneurysm and bypass (8.15 x 1.35), abdominoplasty (1.46 x 0.15), mammoplasty (0.77 x 0.00), herniorrhaphy (5.07 x 1.17) and prostatectomy (7.94 x 2.01) surgeries.

In the other trauma-orthopedic procedures (hip and knee prosthesis), cardiac surgeries and aesthetic liposuction procedures, no significant difference was found in the SSI rate (Table 2).

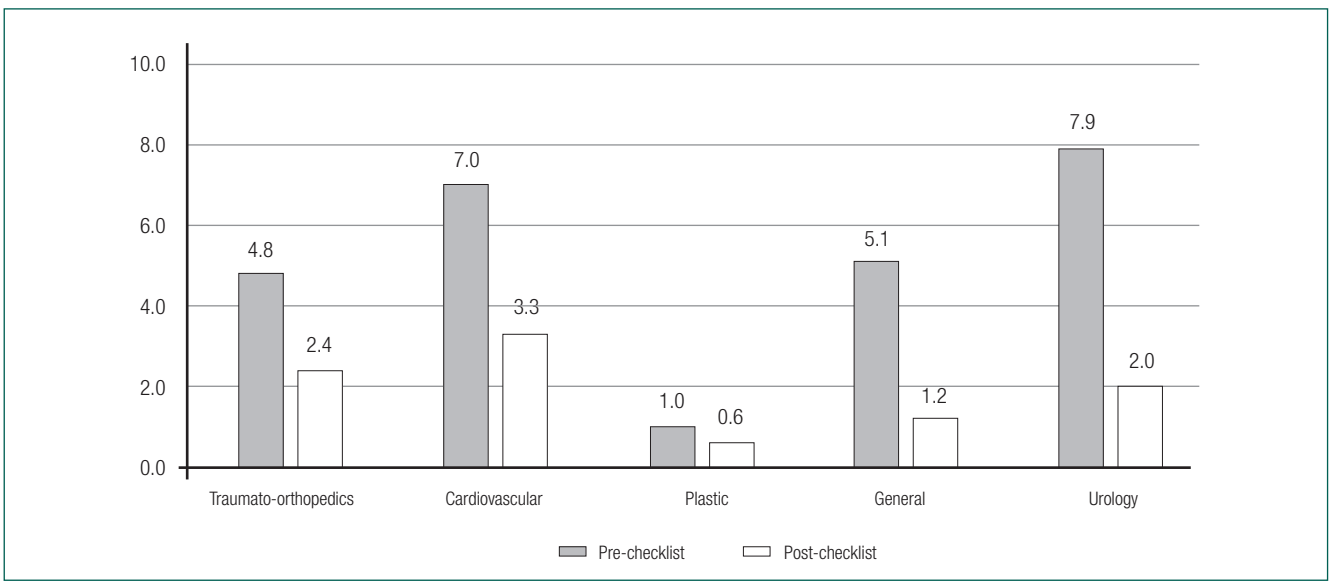

Figure 1. Surgical site infection rate, stratified by surgical specialty, comparing the pre and post implementation period of the surgical safety checklist

Table 2. Infection rate by surgical site, stratified by surgical procedure, comparing the period before and after implementation of the surgical safety checklist

Procedures	Pre-implementation (2006-2009)			Post-implementation (2011-2014)			p- value*	RR	CI 95%
	Surgeries	SSI		Surgeries	SSI				
	n	n	(%)	n	n	(%)			
Spine	947	56	(5.91)	1317	32	(2.43)	<0.001	0.41	(0.27-0.62)
Hip prosthesis	473	15	(3.17)	592	9	(1.52)	0.07	0.48	(0.21-1.08)
Knee prosthesis	43	0	(0.00)	444	16	(3.60)	0.38		
Coronary artery bypass grafting	173	14	(8.09)	147	12	(8.16)	0.98	1	(0.48-2.11)
Other cardiac surgeries	122	4	(3.28)	73	4	(5.48)	0.34	1.67	(0.43-6.48)
Aneurysm and bypass	233	19	(8.15)	446	6	(1.35)	<0.001	0.16	(0.06-0.39)
Abdominoplasty	754	11	(1.46)	1311	2	(0.15)	<0.001	0.1	(0.02-0.47)
Mammoplasty	911	7	(0.77)	1755	0	(0.00)	<0.001		
Liposuction	94	0	(0.00)	1665	1	(0.06)	0.64		
Herniorrhaphy	1202	61	(5.07)	1789	21	(1.10)	<0.001	0.23	(0.14-0.38)
Prostatectomy	529	42	(7.94)	299	6	(2.01)	<0.001	0.25	(0.10-0.58)
Total	5481	229	(4.17)	9838	109	(1.10)	<0.001	0.25	(0.20-0.32)

*chi-square test ; SSI – surgical site infection; RR – relative risk; CI – confidence interval

Discussion

Important advances in the quality aspect and patient safety have been evident in recent years, but in a slower manner than what was expected. The complex segment of the health area continues to operate with a low degree of reliability, and patients suffer preventable injuries during the process of care.[18]

Monitoring and implementing effective strategies for prevention of HAIs in health care facilities has been stimulated and driven by worldwide patient safety movements.[8] Surgical site infections are characterized as preventable adverse events and are indicators of low quality of care; reduction of these requires the efforts of professionals and health institutions.[2]

In this study, when analyzing the incidence of SSI in clean surgeries, before and after the checklist implementation, which is a patient safety strategy proposed by the WHO,[7] a significant reduction in the comparison of SSI rate between the two periods was evidenced.

The Haynes pilot study[9] validated the 19 items that would be used in the surgical safety checklist proposed by the WHO,[7] and showed a reduction of 6.2% to 3.4% (p<0.001) in SSI rates after implementation of the checklist, in a sample with 7,688 patients undergoing surgical procedures and diverse potential contamination (except cardiac surgery), in eight centers around the world. The reduction identified in this study was from 4.17% to 1.10% (p<0.05) in a sample of 15,319 patients and, unlike the pilot study, only procedures classified as clean surgeries of a single center were selected, following the same methodology of epidemiological surveillance over the years of the study. The identified risk reduction, including all procedures analyzed, was 75% when the checklist was administered (RR 0.25; CI 0.20-0.32).

Following Haynes's study,[9] others were published[19-21] showing improvements in the care outcomes, culminating in a meta-analysis that demonstrated a 43% reduction in the risk of surgical infection (RR 0.57, CI 0.41-0.79) with the use of the checklist.[10] A systematic review[13] published in 2016, involving 25 studies, demonstrated reduction of complications, mainly in developing countries.

Contrary to this evidence, a Canadian study that evaluated the implementation of the checklist in 130 hospitals, with 109,341 procedures analyzed pre-implementation and 106,370 post-implementation did not show a significant reduction in the risk of complications, readmissions, and mortality related to the operative procedure.[22] Additionally, the study by Boaz[23] that aimed to analyze the effects of the implementation of the checklist in orthopedic surgeries, did not demonstrate a significant reduction in the rate of surgical infection and other postoperative complications.

The pathogenesis of SSI is multifactorial; depending on factors related to the patient, the sur-

gical team, the procedure, and the contamination of the surgical site by microorganism during surgery, with the latter being a determining factor. Preventive measures are established in the literature, and there is strong evidence for: adequate use of antibiotic prophylaxis; avoiding trichotomy, a blood glucose control in the immediate and preoperative period; maintaining normothermia throughout the perioperative period; optimizing perioperative tissue oxygenation; preparing the skin with alcohol solutions; and, monitoring infection using active surveillance.[1-3]

Although the evidence is well defined, the adherence to these measures in hospital practice turns out to be a challenge due to the complexity of the system, the limitation of human resources, materials and equipment, workload, lack of knowledge, and inefficient management, among other factors.

The administration of an antimicrobial at the right time is an important factor for the prevention of SSI, and the low adherence to the recommended time can contribute to this outcome, as previously demonstrated.[24,25] The use of the checklist can support adherence, and this study demonstrated that the impact factor for SSI reduction was the adherence to the antibiotic administration schedule evidenced by checking antibiotic prophylaxis in the second period of the checklist administration, before the skin incision. During the period prior to the implementation of the checklist, there was no institutional control of proper surgical prophylaxis.

The amount of patients followed in the post-intervention period in this study was higher, mainly due to the increase in aesthetic plastic surgery performed at the institution, which was a strategic definition to optimize the surgical center, and could be a limiting factor. However, even excluding procedures of this specialty, the pre-implementation infection rate was 5.7% and the post-implementation rate was 2.1% ($p<0.001$), showing statistical significance.

Another limitation is the retrospective study design. Significant reduction in infection rates can be influenced by heterogeneity in the groups evaluated, and by demographic characteristics and severity of the patients, which were not assessed.

In contrast to the limitations, the strict maintenance of the pre- and post-intervention conditions, such as the diagnostic criteria of infection, and the methodology of epidemiological surveillance performed by IPCS, were the same in both time periods, without increase in technological resources or change in surgical and anesthetic teams over this period, and no alterations in the material sterilization routines were incorporated. The only intervention included was the implementation of the checklist, which included surgical prophylaxis prior to the surgical skin incision, inferring that this was the impact factor for reduction of the SSI rate.

Conclusion

This study compared the incidence of SSI in clean surgeries of some specialties in the pre- and post-implementation period of the surgical safety checklist proposed by the WHO, and showed a significant SSI rate reduction in the post-intervention period. The incorporation of the checklist into surgical care routines contributed to SSI reduction, improving patient safety.

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Collaborations

Prates CG, Stadñik CMB, Bagatini A, Caregnato RCA, and Moura GMSS contributed to the study design, data analysis, article writing, relevant critical review of the intellectual content, and final approval of the version to be published.

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