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JHQ 139 - Prevention of Postoperative Mediastinitis: A Clinical Process Improvement Model

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In a prospective study of more than 4,000 consecutive patients who underwent any cardiovascular procedure requiring sternotomy incision in a 650-bed tertiary care hospital, a gradual increase in deep sternal infections from 0.8% in 1995 to 2.1% in 1999 was noted. By using a Plan-Do-Check-Act process improvement model, several interventions to decrease the infection rate were planned and implemented based on hypotheses generated from the characteristics of infected patients. These interventions included chlorhexidine preoperative shower, discontinuation of shaving, administration of antibiotics in the holding area, segregation of instruments, and implementation of an insulin protocol. Findings included a decrease in deep sternal and leg infections after implementation of these interventions. Deep sternal infection rates decreased from 2.1% to 1.5% and leg infection rates, from 1.93% to 0.47%. Results were not statistically significant but were clinically relevant. Furthermore, a total of $200,000 was achieved in cost savings in 1 year.

Cardiac surgery is performed on more than 600,000 patients in the United States yearly (American Heart Association, 2001; McConkey et al., 1999). Postoperative mediastinitis is one of the devastating complications of this procedure. The reported incidence ranges from a fraction of a percentage to more than 2% for all cardiac surgery operations in the United States (Bitkover & Gardlund, 1998; Borger et al., 1998). Mediastinitis develops as a result of a complex interaction of patient, surgical, and virulent microbial risk factors. Major consequences include at least two additional operations; increased morbidity and mortality, with extended hospitalization of an average 30 days; and significant economic loss, ranging from $20,000 to $60,000 as direct attributable costs per infected patient (Gaynes et al., 1991; Hollenbeak et al., 2000; Kirkland, Briggs, Trivette, Wilkinson, & Sexton, 1999; Lazar et al., 1995; Ridderstolpe, Gill, Granfeldt, Ahlfeldt, & Rutberg, 2001; Zoutman, McDonald, & Vethanayagan, 1998).

From an epidemiological standpoint, the infection is difficult to control because it generally occurs intermittently and is of multifactorial etiology. Important risk factors may differ between institutions and from one time to another within the same institution. Patients who developed mediastinitis showed a 5-year survival rate 25% lower than those without the condition (Braxton et al., 2000). For these reasons, prevention and control of postoperative mediastinitis have become vital components of hospital infection control and quality management and process improvement programs. A limited number of studies address the efficacy of specific infection control interventions following cardiac surgery (McConkey et al., 1999). Therefore, a clinical process improvement model was developed to study the effects of various interventions in patients undergoing cardiac surgery at a tertiary-care facility over a 12-month period.

Methods

Shadyside Hospital is a 486-bed tertiary-care facility affiliated with the University of Pittsburgh Medical Center. The division of cardiovascular surgery performs approximately 1,000 cardiac surgery procedures requiring sternotomy incision each year. Notably, 80% of the procedures involve saphenous vein grafting (SVG). The cardiothoracic surgical attending staff perform the cardiac surgical procedure requiring a sternotomy incision, while surgical assistants perform the saphenous vein harvesting. The infection control department oversees all cardiac surgery patients from admission through discharge, including postdischarge outpatient follow-up.

The infection control department initiated a prospective cohort, single institution, and hospital-based study of more than 1,200 consecutive cardiac surgery patients from 1995 to 1999. *Mediastinitis* was defined as instability of the sternum with purulent drainage from the sternotomy wound, necessitating a return to the operating room within 30 days of cardiac surgery. All the procedures within the stated time were included, and no exclusion criteria were stated or needed in the study design. All the data were collected by open chart review and entered into the Society of Thoracic Surgeons (STS) database software. The procedures were consecutive entries and complete as required by the STS. Independent review board approval was not necessary because the data were used for quality improvement, the information was de-identified, and no confidential patient-associated information was used.

Statistical Methods

Operative data were retrieved from the STS Apollo (Lumedx®) data management system, and financial data were retrieved from the hospital corporate database (Oracle®). Numerical data are expressed as the mean and one standard deviation. Categorical variables are given as the proportion of total cases in the appropriate sample and expressed as a percentage. Univariate statistical significance for numerical data was determined by the Student’s t-test or by the Mann-Whitney rank sum test for data not normally distributed. Analysis of categorical variables was done using chi-square or Fisher’s exact test where appropriate. All univariate testing was two-tailed with the type 1 error set up at $p < 0.05$.

Initial Data Analysis

A retrospective review of historical postoperative surgical site infection data following cardiac surgery in the same institution along with the use of the STS Apollo (Lumedex) data management system revealed a gradual increase in incidence of mediastinitis, from 0.8% in 1995 to 2.1% in 1999 (**Table 1**). This increase was noted when the data were compared to the risk-adjusted predicted probability of mediastinitis using a logistic regression model from Dartmouth-Hitchcock Medical Center, Lebanon, NH (see **Table 2**). This model was developed by the Northern New England Cardiovascular Disease Study Group and adopted for this study (Charles A. Marrin, personal communication September, 1999). Patients who underwent SVG harvesting had higher rates of infection. These infections were predominantly caused by staphylococcal species that compose normal skin flora (**Table 3**). One-third of infected patients did not receive a preoperative antiseptic shower or appropriate preoperative antibiotic prophylaxis. Surgical assistants and surgical instruments were shared between the SVG and mediastinum. Patients with diabetes had twice the rate of infection as nondiabetic patients (see **Table 4**). Analysis of various diagnosis related groups pertaining to cardiac surgery procedure revealed an increase in unrecoverable cost, on average, of $20,000 per patient in those who developed mediastinitis (see **Table 5**).

Interventions

In April 1999, a clinical process improvement was initiated based on the Plan-Do-Check-Act (PDCA) model, a continuous improvement cycle originally developed in the 1930s by Walter Shewhart and popularized by quality management expert Edward Deming in the 1950s (see **Figure 1**; Deming, 1986; Shewhart & Deming, 1939). The goal was to develop and implement a risk-adjusted measurement system to track the occurrence of mediastinitis over time. Based on initial data analysis, hypotheses were generated regarding process improvement that could significantly decrease the rate of postsurgical infection and regarding appropriate interventions based on benchmarking, expert review, key characteristic features of infected cases, and the review of the medical literature (Baskett, MacDougall, & Ross, 1999; Borger et al., 1998; Classen et al., 1992; Furnary, Zerr, Grunkemeier, & Starr, 1999; Hussey, Leeper, & Hynan, 1998; Latham, Lancaster, Covington, Pirolo, & Thomas, 2001; Mangram, Horan, Pearson, Silver, & Jarvis, 1999; Ridderstolpe et al., 2001; Roy, 1998; Zacharias & Habib, 1996).

The following new interventions were instituted. A dedicated, full-time infection control practitioner (ICP) was assigned to the open-heart surgery program. Under the supervision and guidance of the medical director of infection control/hospital epidemiologist, the ICP prospectively followed all cardiac surgery patients from time of admission until discharge, including postdischarge follow-up of those readmitted within 30 days. The ICP focused on implementing a seven-part infection control intervention program, as follows:

- prospective surveillance of superficial and deep chest and leg infections
- postdischarge follow-up of patients readmitted within 30 days
- chlorhexidine showers by the patient the night before and the morning of the surgery
- hair removal only if necessary by clipping on the morning of surgery
- administration of antibiotic prophylaxis (Cefuroxime or Vancomycin) in the holding area with repeat intraoperative doses if needed
- segregation of surgical instruments between SVG harvest site and chest
- improved glycemic control in diabetic patients.

In addition, all patients undergoing elective cardiac surgery received a preoperative bathing education sheet and chlorhexidine scrub brushes (see **Figure 2**). A dedicated pharmacist in the holding area implemented a standardized protocol for antibiotic prophylaxis, defined as administration of antibiotics 2 hours prior to surgical incision in accordance with Joint Commission on Accreditation of Healthcare Organizations standards (Classen et al., 1992). To eliminate cross-contamination, instruments between the SVG harvest site and the chest were segregated and separate surgical assistants were assigned to each surgical site.

A subcommittee was formed to develop and implement an insulin protocol for improved glycemic control in patients with diabetes. After multiple trials of various insulin protocols, a simplified high-infusion protocol replaced the low-infusion protocol with intermittent boluses. The medical director of infection control/hospital epidemiologist performed periodic observations of all cardiac surgery patients to monitor and reinforce compliance of these protocols. The ICP gathered and analyzed the data reported to the division of cardiovascular surgery, the infection control committee, and the quality management committee.

Results

Between January 1999 and December 2000, 2,364 cardiac surgery procedures were performed. The new infection control model was instituted in April 1999 with all interventions implemented as outlined above. Preoperative antiseptic shower compliance rose from 70% to 92%. The administration of appropriate antibiotic prophylaxis increased from 70% to 89%. The new insulin protocol, a simplified high-infusion protocol, had a high rate of acceptance by the nursing staff. Glycemic control improved and a mean blood sugar of 155 mg/dl was achieved in all diabetic patients. In addition, the rate of mediastinitis declined from 2.1% in 1999 to 1.5% in December 2000 (see **Table 6**); these results were not statistically significant ($p = 0.349$) but were clinically relevant. The leg wound infection rate declined from 1.93% to 0.47% (see **Figure 3**), which was statistically significant with $p < 0.001$. The case mix did not change over the study period. The implementation of these successful infection control interventions resulted in cost savings of $200,000 to the institution over 1 year. This was a true cost, not an estimate.

Conclusions

This article illustrates an example of a successful outcome of a clinical process improvement model. However, the traditional randomized controlled study in which each variable is evaluated one at a time was not used; this type of study requires enormous resources and many tiers of data collection to obtain adequate statistical power for analysis. A reduction in surgical site infection rate was achieved by implementing a rapid PDCA cycle (see **Figure 1**) for multiple infection control interventions from April 1999 to December 2000. Even though the decrease in mediastinitis rates was not statistically significant, the trend was in the right direction, with decreased rates of morbidity and mortality and shorter lengths of hospital stay. These interventions resulted in a significant economic benefit to the institution of more than $200,000 over 1 year.

The Study of the Efficacy of Nosocomial Infection Control data demonstrated that a comprehensive approach for the prevention of surgical site infections (SSI) resulted in 31% lower rate of SSI (Haley et al., 1985). A major advantage of the PDCA process is that multiple variables based on data and characteristics of infected patients are evaluated simultaneously for changes that result in clinical improvement. Another important advantage of this clinical process improvement model is that it is replicable across institutions. O'Connor et al. (1996) of the Northern New England Cardiovascular Study Group emphasized that the efficacy of only an entire intervention—not the individual components—can be interpreted in the complex setting of modern cardiovascular care. Adoption of a similar program at other institutions would be practical and cost effective for control and prevention of mediastinitis in cardiac surgery patients. Additional studies are needed, however, to evaluate the efficacy of such programs in other surgical subspecialties.

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Author's Biography

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Core CPHQ Examination Content Area

II. Information Management

Objectives

By participating in this independent study offering, the reader will be able to do the following:

1. Design a clinical process improvement model (PDCA) to study postoperative mediastinitis.

2. Evaluate several interventions to decrease the infection rate using the PDCA model.

3. Summarize the findings with emphasis on clinical and economic benefits of a PDCA process.

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