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ORIGINAL ARTICLE

Effectiveness of Surgical Care Bundle to Reduce Surgical Site Infections in Patients Having Cardiac Surgery

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Surgical Care Bundle, Surgical Site Infection (SSI), Cardiac Surgery

ABSTRACT

Background: *Surgical Site Infections (SSIs) are the most commonly healthcare-associated infections among patients undergoing surgical procedures. Reaching zero % SSI rate seems to be impossible target, although most of them are easily preventable through effective preventive strategies.* ***Objective:*** *we aimed to evaluate application of a "surgical care bundle" on patients undergoing cardiac surgeries, with the goal of reducing overall SSI rates.* ***Methodology:*** *This interventional study was conducted on two groups of patient: The baseline group consisted of patients having cardiac surgery during a 16-month period of time from January 2012 till April 2013, while the intervention group included patients having cardiac surgery during a 16-month period of time fsrom January 2014 till April 2015, a preparatory period was from (May 2013 till December 2013) in between the 2 periods of time to educate, raise the awareness and build capacities to implement the surgical care bundle and finally reach at least 90% compliance with the bundle. SSI rates were calculated among two patient groups. SSI microbiology was noted; microorganisms were isolated and culture of wound swab or aspirate from patients with SSI, and were identified based on standard microbiological techniques. Every Patient with SSI was followed up for six months to detect mortality from infection.* ***Results:*** *A 4 years study showed a high statistically significant decline in the SSI rate average from 5.9% in baseline group 1.9 % in the intervention group (P value < 0.001).The rate of SSI caused by MRSA revealed a highly statistical significant decline in the patients having SSI in the intervention group 8.01; compared to the baseline group 29.6 (P value < 0.001). Also there was a statistically significant decline in the rate of SSI caused by MDROs from 41.8% in baseline group and 11.6% in the intervention group (P value < 0.05). Probability of survival increased in the intervention group; as the mortality from infection decreased.* ***Conclusion:*** *Strict adherence to surgical care bundle reduced the overall SSI rate, and decreased its rate when caused by MRSA &MDROs in post cardiac surgery patients.*

INTRODUCTION

Surgical site infections (SSIs) are frequent and serious complications of surgical procedures. They are associated with a long hospital stay, readmissions, re-interventions and increased morbidities and mortalities.[1]

SSI is one of the most preventable nosocomial infections. Despite the widespread international introduction of level I evidence-based guidelines for the prevention of SSI, such as that of the National Institute for Clinical Excellence (NICE) in the UK and the surgical care improvement project (SCIP) of the USA. SSI rates have not measurably been fallen in comparison to the effect of bundle approach which was efficient in deceasing SSIs in many studies. The surgical care bundle approach is a collection of standardized clinical practices that have been individually shown to improve outcome. Implementation of care bundle measures together was believed to result in the best outcome compared to practicing individual measures by themselves. The care bundle approach must be applied into routine care for all patients from day zero of the procedure. They are considered important tools to improve the process of care and thereby the outcome for the patient. [2]

The surgical care bundle; includes methicillin resistant *Staphylococcus aureus* (MRSA) screening (in high risk operations as cardiac surgeries, orthopedic surgeries and neuro surgeries) for decolonization or vancomycin as surgical prophylaxis according to the hospital policy, methods for preoperative removal of hair (where appropriate), rational antibiotic prophylaxis,

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effective skin preparation, avoidance of perioperative hypothermia, and management of perioperative blood glucose level . [2]

Superficial and deep incisional SSI are relatively frequent complications after cardiac surgery and are associated with substantial morbidity and mortality, with an incidence of up to 15%. The normal skin flora is a complex ecosystem formed by the normal microflora of 10^{14} microbes and 10^{13} mammalian cells. The intact skin is resistant against microbial invasion due to relative dryness, cell-mediated immunity and antibody production. However, the type and virulence as well as the quantity of inoculated bacteria are important factors to implicate a SSI.[3] ***Our aim was*** *to evaluate the effect of application of a "surgical care bundle" for patients undergoing cardiac surgeries, with the goal of reducing overall SSI rates.*

METHODOLOGY

This work was a 4 years interventional study in a tertiary cardiac surgery center in Cairo, Egypt. The study was done on two groups of patients. The baseline group consisted of patients undergoing cardiac surgery during a 16-month period of time from January 2012 till April 2013, and the intervention group including patients having cardiac surgery during a 16-month period of time also from January 2014 till April 2015, after a preparatory period from May 2013 till December 2014. This period was to educate, raise the awareness and build capacities to implement the surgical care bundle. Intervention phase starts after reaching at least 90% compliance with the surgical care bundle. We prospectively implemented multiple interventions, with retrospective analysis of data (SSI rate, endemic rate of SSI and outbreak threshold in cardiac surgeries). The overall, superficial, deep, and organ/space SSI rates were compared before and after implementation of this surgical care bundle.

Baseline group: (patients undergoing cardiac surgeries from January 2012 till April 2013):

SSIs epidemiologic surveillance program, a designated surveillance form was used for all patients undergoing cardiac surgeries. The data were recorded daily including administrative data (hospital number, admission date), demographic risk factors (age, gender, severity of underlying illness, primary diagnosis, diabetes mellitus , smoking, obesity, and immunological status), if a patient acquired SSI, the date of onset was also recorded. SSI definition was based on Centers for Disease Control and Prevention(CDC): [4]

Superficial incisional SSI was defined as infection that occurs within 1 month after cardiac surgery and involves only the skin or subcutaneous tissues of the incision. **Deep incisional surgical site infection:** The infection occurs within 30 to 90 days after of cardiac surgery and the infection involves deep soft tissues of the incision. **Mediastinitis:** Infection occurs within 30 days or within 90 days after cardiac surgery and infection involves mediastinum, excluding the skin incision, fascia, or muscle layers that is opened or manipulated during the operative procedure.

SSI rate was calculated as: Number of patients having SSI post cardiac surgery/total no of patients undergoing cardiac surgery × 100. Endemic rate (Average) and outbreak threshold (Endemic rate + Standard deviation) were calculated for the 16 month reading of cardiac SSI rates. Every Patient with SSI was followed for six months to detect mortality from infection and detect rate of survival in relation to time.

Intervention group: (patients undergoing cardiac surgeries from January 2014 till April 2015): The same design of the surveillance program, the same data were collected and the same definition of term of SSI, with the application of surgical care bundle compliance 90%.

Preparatory period: (from May 2013 till December 2013): several interventions were implemented for SSI prevention. Education and training activities (especially on job training) were implemented in the form of seminars and workshops for all staff, display of posters calling for use surgical care bundle. Surgical care bundle was implemented with checklists and compliance monitoring. The bundle includes: preoperative actions: MRSA screening was done as a routine test for all patients will have cardiac surgery by nasal and groin swab which were cultured immediately. Decolonization was done according to MRSA decolonization regimen predesigned by infection control team and it was only for MRSA carriers. Regimen was applied 10 days before surgery by 2% mupirocin cream to both nares and all open or colonized wounds three times a day and chlorhexidine shower for bathing. And perioperative actions: Removal of hair with medical clipper within 1 hour before surgery, then patient take a perioperative shower using chlorhexidine. Designing and implementation of an antibiotic policy using cefazolin as standard protocol (1 to 2 gm IV) administered 30 to 60 minutes during induction of anesthesia, followed by 1 g every 8 hours and stopped 48 hours after operation, or vancomycin as alternative regimen (1 gm IV) (If there is MRSA outbreak or MRSA carriers without decolonization or type I allergy to penicillin) started 60 minutes before surgery followed by 1 g every 12 hours for 48 hours as surgical prophylaxis, cefazolin was started with the induction of anesthesia and stopped 48 hours after operation after surgery. Effective skin preparation using iodophore10 % in one direction using single use dressing, avoidance of perioperative hypothermia, and management of perioperative blood glucose maintaining a glucose level <11mmol/l or < 198mg/dl . Any diabetic patient will be on insulin infusion perioperative and postoperative according to predefined scale in our hospital. The antibiotic choice, dosage, hypersensitivity test and

management of glucose level were the complete responsibility of the anesthesiologist according the predesigned protocols [5].

The adherence to surgical care bundle was measured by the following indicators:

a. Appropriate antibiotic choice:

Number of patients who received the appropriate prophylactic antibiotic
All patients for whom prophylactic antibiotics are indicated

b. Appropriate timing of prophylactic antibiotics:

Number of patients who received the prophylactic antibiotic within 1hr prior to incision (2hr: vancomycin)
All patients for whom prophylactic antibiotics are indicated

c. Appropriate hair removal:

Number of patients who had hair removed with clippers
Patients undergoing cardiac surgery

d. Normothermia:

Number of patients with postoperative temperature ≥36.0oC
Patients undergoing cardiac surgery

e. Glucose control:

Number of cardiac surgery patients with glucose control at 6AM POD1 and POD2 (operation = POD0) **
Patients undergoing cardiac surgery
**POD: Post-Operative Day

Microbiological techniques:

a. Disc diffusion Method:

The organisms were isolated by culture of wound swab or aspirate from patients with SSI and identified based on standard microbiological techniques**.** The susceptibility of the clinical isolates to some routinely used antibiotics was determined by the Kirby-Bauer disk diffusion method: Azithromycinc, clindamycin, cefoxitin, penicillin and trimethoprim-sulfamethoxazole were tested for *Staphylococcus spp.* cefoxitin disk diffusion test was used to detect methicillin-resistant *S.aureus*(MRSA) when zone of inhibition ≤ 21 mm. Ampicillin, ciprofloxacin, ceftriaxone, ceftazidime, gentamicin, amikacin, and meropenem were tested for Enterobacteriaceae, Amikacin, gentamicin, ceftazidime, ciprofloxacin, meropenem, colistin, piperacillin-tazobactam and ticarcillin were tested for *Pseudomonas spp.* Combination disk method using both cefotaxime and ceftazidime, alone and in combination with clavulanic acid, was performed for detection of extended spectrum beta-lactamase (ESBL) among the members of Enterobacteriaceae. Five mm or more increase in zone of inhibition for either cefotaxime-clavulanic acid or ceftazidime-clavulanic acid disk compared to the cefotaxime or ceftazidime disk respectively was taken as confirmatory evidence of ESBL production[6]. ***b. Multidrug Resistance Organisms (MDROs) detection*:**

MDROs are defined as bacteria that are resistant to one or more classes of antimicrobial agents. ***c. MRSA screening:*** Rubbing the inside circumference of each anterior nares was done for 3 to 5 seconds to obtain adequate sampling. Specimens were inoculated onto CHROMagar MRSA (MR500), which were incubated for 20 to 28 hours at 35°C to 37°C. After 24 hours, we interpreted rose to mauve colonies present on both plates as MRSA [7].

Statistical Methods:

Statistical analysis was done on a personal computer using the Statistical Package for Social Sciences (SPSS) version 21 as follows: Comparative statistics for 2 groups by Mean ,SD ,student t test for quantitative data , Pearson correlation test and rate of survival by Kaplan-Meier plot estimate.

RESULTS

The number of patients who were admitted to the hospital in between 1st of January 2012 till 30th of April, 2013; they were 2275 patients in the base line group undergoing cardiac surgery. The intervention group 2425 patients were admitted to the hospital and were undergoing cardiac surgery from 1st of January 2014 till 30th of April2015. The period from 1st of May 2013 till 31st of December 2015, was a preparatory phase in which the surgical care bundle was applied and compliance rate reached 95% by the end of the phase.

Compliance with surgical care bundle increased from 20% in May 2013 to 95% in December 2013; SSI rate showed a highly statistical significant decline (P value < 0.001) in relation to bundle compliance. Also each element of the bundle had a highly significant negative correlation to SSI (P value < 0.001; correlation coefficient towards -1) (Figure 1).

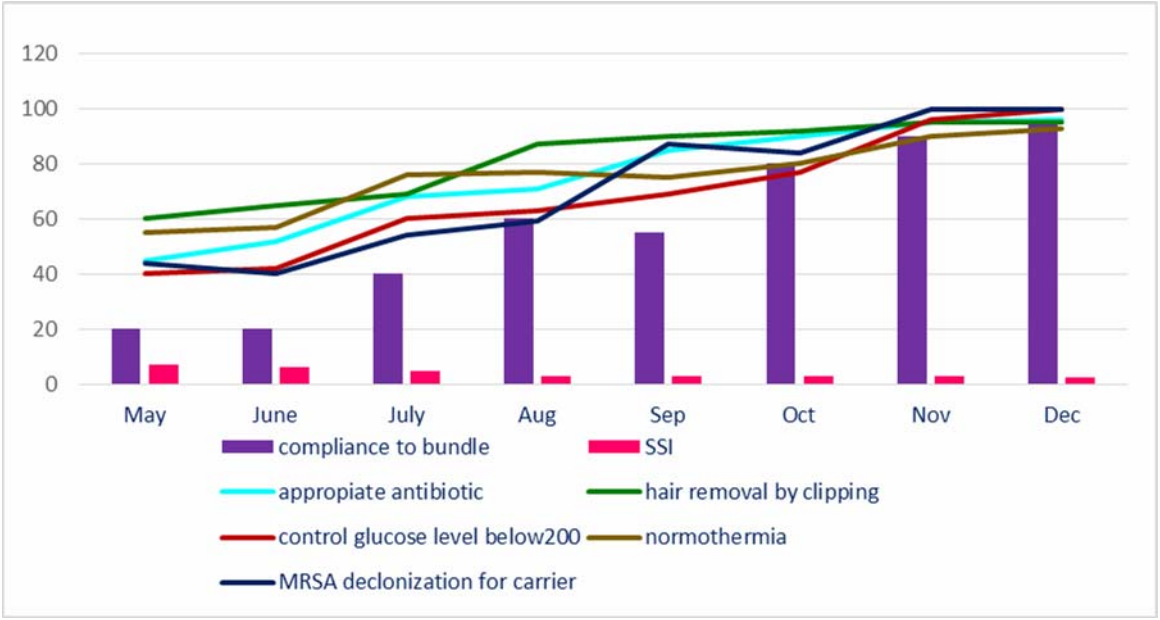

Fig. 1: Compliance with bundle and its individual component in the preparatory phase

Our results showed a highly statistical significant decline in SSI rate between intervention group (1.9%) as compared to the base line group (5.9%) and (P value <0.001) throughout 16 month. The outbreak threshold also decreased from 7.2 in the base line group to 2.7 in intervention group with highly statistical significance (P value <0.001) .the results are shown in table 1& figure 2.

Table 1: Comparison of the IR in the Baseline group& Intervention group

Groups	No of patients having SSI	Outbreak Threshold (Endemic rate + Stand. Dev.)	Infection Rate Mean ± Stand. Dev.	t value	P value
Baseline group	135	>7.2	5.9±1.3	10.8	**< 0.001 HS*** **
Intervention group	49	>2.7	1.9±0.7		

*****Highly significance.

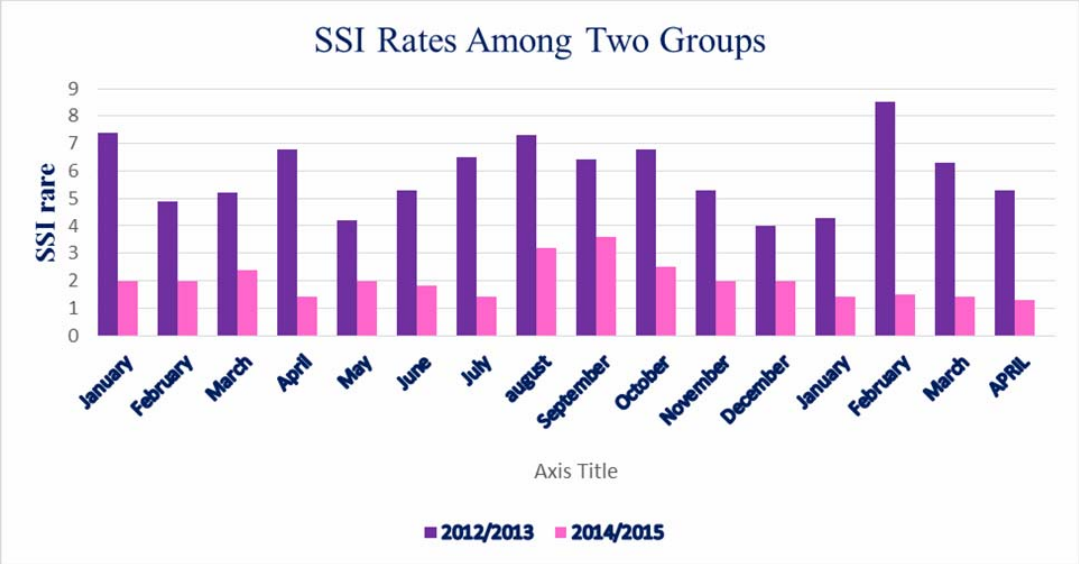

Fig. 2: SSI rates among two groups

Figure 3 showed an obvious decrease in the rate of SSI caused by MRSA in the intervention group with average 8.01%, versus baseline group the average was 29.6 % with a highly statistical significance difference (P value 0.001).

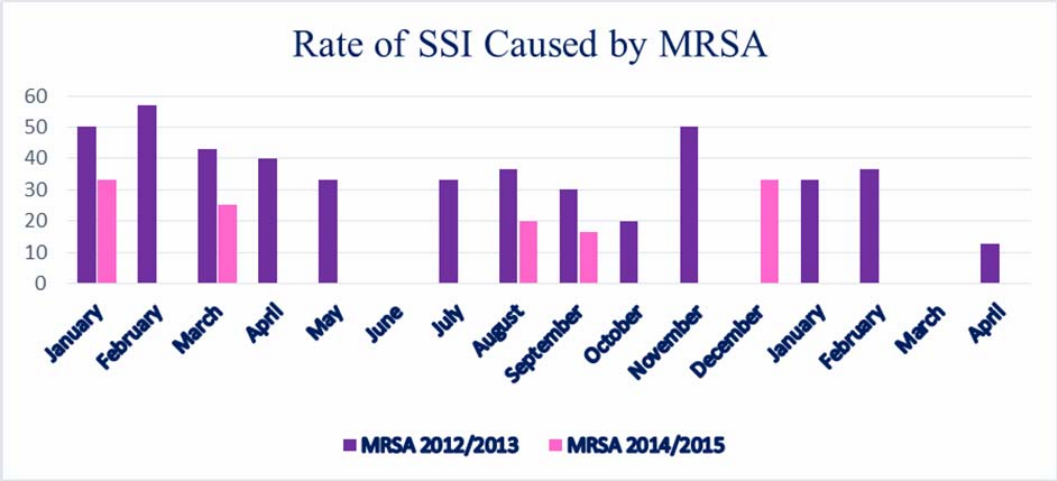

Fig. 3: The rate of SSI caused by MRSA among the two group

In general the most commonly isolated organisms in the two groups was *Klebsiella pneumoniae 60%* . Figure 4 showed a statistical significant decrease of SSI rate caused by MDROs in the intervention group (Mean =11.6) in comparison to baseline group (Mean =41.8), (P value < 0.05). *Klebsiella pneumoniae* showed multidrug resistance in *56% , followed* by *Escherichia coli in 32% of the cases.*

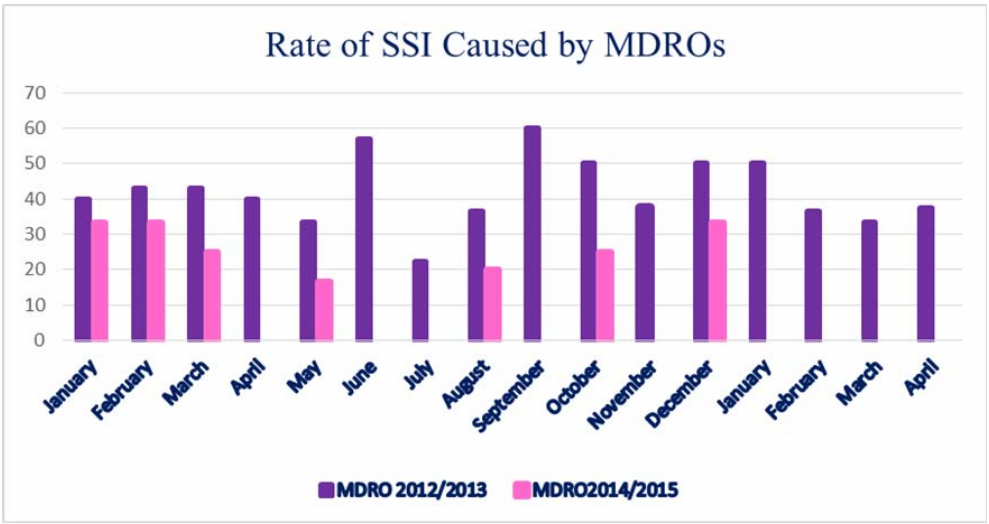

Fig. 4: The rate of SSI caused by MDROs among the two group

Most of patients died in the first 2 month of the follow up period. The probability of surviving in patients had post-operative SSI in a 6 month of follow up was increasing in the intervention group in comparison to the baseline group as shown in figure 5.

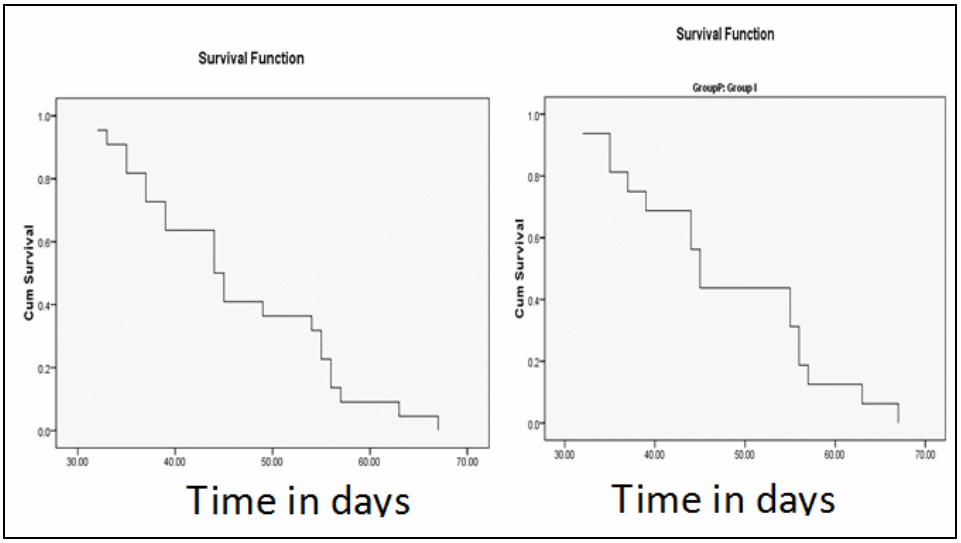

Fig. 5: Plots of Kaplan-Meier product limit estimates of survival of a group of patients having SSI post cardiac surgery

DISCUSSION

One of the most serious and frequent complication after cardiac surgery is SSI, the implementation of surgical care bundle in our hospital was associated with high significant decrease of SSI rate. The relevance of this improvement is obvious, considering the serious consequences associated with SSI.

Bundle compliance was measured from May 2013 till December 2013and increased from 20% to 90% it coincides with those found by the study of *Crolla et al.* [8] , who measured bundle compliance and reported an increasing in the compliance from 10% to 80%.

In our study, SSI rate was decreasing with a highly significant trend after implementation and strict adherence to surgical care bundle in the intervention group in comparison to the baseline group with high statistical significance (Pvalue <0.001). This was in agreement with *Van der et al.*[9] , who reported that SSI-rate declined significantly between 2009 and 2011. These results agreed also with the results of *Jiang et al.*[10], who observed a clear decrease in the annual incidence rate of SSI (from 6.21% in 2008 to 2.28% in 2013) due to implementing SSI prevention program. Similar results were found by *Lutfiyya et al.*[11], who implement an improvement project to decrease SSI reaching an absolute decrease of 14.49% was highly significant ($p < 0.0001$) in colorectal surgeries. Also our results was similar to a systematic review and cohort meta-analysis done by *Tanner et al.*[12], who documents that surgical care bundles have a clinically important impact on reducing the risk of SSI compared to standard care with a CI of 0.55 (0.39–0.77; P = .0005). *Finkelstein et al.*[13], observed significant reductions in organ/space infection rates, particularly mediastinitis. These differences remained significant when adjusted for potential confounding variables.

MRSA percentage was calculated in the two groups and showed a high statistically significant decrease from 29.69% in the baseline group to 8.1% in the intervention group. Our results agreed with a 39 studies were included in systematic review and meta-analysis; showing that nasal decolonization had a significantly protective effect against surgical site infections associated with MRSA [14]. Similar results were reported by *Chien et al.*[15], who reported that Care bundle was protective against MRSA infection and found that surgical care bundle can decrease the incidence of SSI post cardiac surgery effectively, especially infection caused by MRSA.

We found that most patients died in the first 2 months of the follow up period, it's a logic trend of death from infection. The probability of surviving in patients had post-operative SSI after a 6 month of follow up was increasing in the intervention group in comparison to the baseline group. Reducing the mortality rate in the intervention group versus base line group was expected depending on decreasing total SSI post cardiac surgery, this result also agreed with the study of *Crolla et al.*, [8].

Our study revealed that the predominant microorganism causing SSI post cardiac surgeries was *Klebsiella pneumoniae,* this result was against many studies, as gram positive bacteria especially *Staphylococcus aureus* and coagulase-negative species are the most common bacteria causing SSI post cardiac surgery. One of these studies study was done by *Lepelletier et al.*[16], who *reported that* the most commonly isolated pathogen was *Staphylococcus*. Another study did not agreed with ours revealing that

MRSA wound infection after cardiac surgery was endemic in the hospital[15]. Another study demonstrated equal frequencies of gram-positive cocci and gram-negative bacteria[17] . Predominate gam negative bacilli is a common trend in Egypt due to lacking antibiotic policies and Stewardship, also it may due to inappropriate skin preparation leading to transfer of gram negative bacilli from perineum and legs to the chest. The present study showed a statistical significant decrease in MDROs percentage in the intervention group in comparison to baseline group, this significant decline may be due to strict adherence to the surgical prophylaxis policy and treatment of infections according to culture and sensitivity.

CONCLUSION

The implementation and strict adherence to surgical care bundle was associated with reduction of the SSI. This makes the surgical care bundle an important tool to improve patient safety.

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