An observational study of the surgical site infection rate in a General Surgery Department at a General Hospital in Malaysia



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Background: Surgical site infection (SSI) is one of the most common healthcare-associated infections globally. A consequence of infection is wound dehiscence with an associated high mortality rate. Method: A surveillance study of SSI was undertaken in a Surgical Department of a General Hospital in East Malaysia to determine the SSI incidence and to identify the risk factors and outcomes associated with SSI. This was a prospective cohort study of 222 patients, who were admitted for either elective or emergency operations. Results: The SSI incidence was 11.7% (n=26) and the risk factors associated with an SSI were male gender (OR 3.47, 95% CI 1.40–8.64; AOR 2.54, 95% CI 0.98–6.55, *p*=0.054) and surgical wounds classified as contaminated or dirty (OR 5.49, 95% CI 2.26-13.34; AOR 4.53, 95% CI 1.82–11.23, *p*=0.001). The re-admission rate was 19.2% and the mean length of stay was 20.5 days (SD=12.4). Additional microbiological data identified that Escherichia coli was the most common isolated pathogen. This study was the first prospective study on SSI incidence in the hospital where the corresponding author works and has helped to establish a baseline SSI rate to inform subsequent audits.

Surgical site infection (SSI) is the second most common hospital-acquired infection (HAI) (Burke, 2003) and is defined as one that occurs within 30 days after a surgical procedure if no implant is left in place, or within 1 year where there is a prosthetic implant (Horan et al, 1992). It is commonly accepted that the risk of SSI increases with the increasing level of contamination of an operative wound (Ju et al, 2014).

The Centers for Disease Control and Prevention (CDC) established a system for monitoring SSI rates based on degree of microbial contamination at time of surgery (Garner, 1986). Subsequently, rates of 1–5% for clean, 3–11% for clean-contaminated, 10–17% for contaminated and over 27% for dirty surgical wounds have been reported (Mangram et al, 1999).

Patients undergoing emergency surgical procedures are believed to be more at risk of developing SSI than those who have elective procedures (Richards et al, 2003). According to Scarborough et al (2016), this is because elective procedures are planned surgeries, where risk factors can be identified and preventive measures can be carried out prior to surgery.

Risk factors for SSI are deemed to be multifactorial (Korol et al, 2013) and include advanced age and gender (Alfonso-Sanchez et al, 2017). Furthermore, an association between SSI and diabetes has also been recognised as an independent risk factor. For example, Trussell et al (2008) showed that diabetes mellitus was an independent risk factor for SSI (p=0.001; OR 4.71) and tight control of blood sugars peri-operatively reduced the infection rate significantly. Systematic reviews have also shown an increased risk of SSI with the presence of diabetes (OR 1.5-24.3 and OR 1.53 respectively) (Korol et al, 2013; Martin et al, 2016). Interestingly, a study by Takesue and Tsuchida (2017) showed that hyperglycaemia in patients with no diabetes was also found to have higher odds of SSI (OR 1.74, CI 1.08-2.81,

Dr Kee Ai Wong, Medical Officer, Wound Care Unit, General Surgery Department, Sarawak General Hospital, Ministry of Health Malaysia Samantha Holloway, Reader, Programme Director, MSc in Wound Healing and Tissue Repair, Cardiff University School of Medicine, Centre for Medical Education College of Biomedical and Life Sciences *p*=0.024) compared to patients with diabetes (OR 1.50, CI 0.16-14.09, *p*>.05).

SSI may also lead to surgical wound dehiscence (Graham and Vijayabhasker, 2016) and becomes more complicated if there is evisceration and formation of an entero-cutaneous fistula (Joyce and Dietz, 2009). These complications have been reported to have a high morbidity and a mortality rate as high as 45% (Ramsay and Mejia, 2010; van Ramshorst et al, 2010). When SSI develops, the wound may require re-exploration to remove any devitalized tissue, such as slough and necrosis, as well as drain any abscesses that may have formed (Spiliotis et al, 2009; Walsh et al, 2009). The consequences of which may be an extended hospital stay, potential re-admission, greater use of wound care products and/or secondary procedures, all of which place an additional economic burden on the healthcare system (Urban, 2006). The mean calculated direct cost due to SSI in Singapore has been estimated to be SGD \$2,160 (US \$1,530) per patient (Liau et al, 2010), as well as potential additional costs and complications due to prolonged hospitalization, susceptibility to secondary infection, pain, anxiety and reduced quality of life (Liau et al, 2010).

Although there are existing projects examining SSI surveillance in Malaysia, publication of the results are rare. Data from an early study in Malaysia identified that SSI accounted for 25.4% of all HAIs (Hanifah, 1990). A more recent study, also in Malaysia, reported a SSI rate of 13.8% (Oh et al, 2014). This suggests a large decrease in the rate, however, Oh et al only examined patients undergoing elective procedures, therefore, the true rate may be higher if emergency procedures are also taken into account. The aim of this prospective study was to identify the incidence of SSI in a General Hospital in East Malaysia and to determine the common risk factors that lead to the development of SSI, as well as investigating the outcomes associated with SSI.

Method

Setting

Sarawak General Hospital (SGH) is the tertiary hospital in East Malaysia that has a total of 765 beds. The surgical department in SGH is the referral centre for the whole state of Sarawak in Malaysia, and performs procedures such as: appendix surgery, bile duct, liver or pancreatic surgery, gallbladder surgery, colon surgery, gastric surgery, rectal surgery, small bowel surgery, spleen surgery and thyroid and/or parathyroid surgery.

Participants

This prospective, longitudinal study included all patients who had either elective or emergency operations between 16th March 2018 and 15th June 2018. All patients were prospectively observed from the day of operation until 30-days post operation.

Table 1 shows the inclusion and exclusion criteria for the study.

Data collection

The data collection tool used in this project was modified from the CDC and National Healthcare Safety Network (NHSN) (Mangram et al, 1999) tool as well as the existing surveillance tool used within the hospital. The researcher (KAW) was the sole data collector and also undertook entry of data.

Table 1. Inclusion and exclusion criteria			
Inclusion criteria	Exclusion criteria		
Age >12	Age <12		
Type of surgery: Appendix Bile duct, liver or pancreatic Gallbladder Colon Gastric Rectal Small bowel Spleen Thyroid and/ or parathyroid Exploratory laparotomy Sign and symptoms of SSI within 30-day surveillance period	Type of surgery: Breast Herniorrhaphy Sign and symptoms of SSI >30-day-surveillance period Surgery performed at other facility but admitted for wound care or other secondary procedures		



Figure 1. Distribution of SSI cases according to type of procedures



Figure 2. Circumstance of when SSI was detected



Figure 3. Type of confirmed SSI



Figure 4. Time and frequency SSI was detected post-operatively

Table 2. Demographic data		
Variable	Total n=222 n (%)	Mean (SD)
Age		45.3 (19.98)
Gender		
Male Female	105 (47.3) 117 (52.7)	
Weight (Kg)		61.8 (12.90)
Height (m)		1.6 (0.08)
BMI		25.0 (4.65)
Comorbidities		
Diabetes Yes No Hypertension Yes No Malignancy Yes	25 (11.3) 197 (88.7) 70 (31.5) 152 (68.5) 47 (21.2)	
Type of procedure Appendix surgery (APPY) Bile duct, liver or pancreatic surgery (BILI) Gallbladder surgery (CHOL) Colon surgery (COLO) Gastric surgery (GAST) Rectal surgery (GAST) Rectal surgery (REC) Small bowel surgery (SB) Spleen surgery (SPLE) Thyroid and/ or parathyroid surgery (THYR Exploratory laparotomy (XLAP)	81 (36.5) 12 (5.4) 42 (18.9) 28 (12.6) 15 (6.8) 10 (4.5) 8 (3.6) - 19 (8.6) 7 (3.2)	
Wound classification Clean Clean-contaminated Contaminated Dirty Nature of surgery Emergency Yes No	19 (8.6) 128 (57.7) 15 (6.8) 60 (27.0) 144 (64.9) 78 (35.1)	

SD= Standard Deviation; BMI= Body mass index

Ethical considerations

Ethical approval for the study was obtained from the Medical Research Ethics Committee, Malaysia and School of Medicine Research Ethics Committee at Cardiff University. Informed consent for data collection was obtained from participants. The study was registered with the National Medical Research Registry (Registration number NMRR-17-3009-39295).

Statistical Analysis

Continuous variables are presented as means ± standard deviation and analysed using independent sample t-test. Categorical variables are presented in number and percent and were analysed using Pearson's Chi-square test. The significant variables in the univariate analyses were compared using backward method in multiple logistic regression analysis. An adjusted odd ratio was used to identify factors associated with SSIs, and *p*-value of less than 0.05 was considered as statistically significant. All statistical analyses were performed using SPSS software (version 21.0; SPSS Inc, Chicago, IL, USA).

Results

Incidence of SSI

The total number of procedures was 222, with 26 cases of SSI detected giving an incidence of SSI of 11.7%. The mean age of patients was 45.3 (SD=18.98) years, and female gender was predominant (52.7%) [Table 2].

Appendix surgeries was the most common procedure performed and was attributable for almost half of the total SSI cases (n=12, 46.2%) [*Figure 1*]. SSI occurred more in contaminated and dirty surgical procedures, i.e. appendectomies (n=18, 69.2%) and emergency procedures (n=23, 88.5%). The majority of SSI

Table 3. Association between numerical and categorical variables and outcome					
Variable		No SSI	Yes SSI	<i>p</i> -value	
			n (%) mean (SD)	n (%) mean (SD)	
Age ^a			46.0 (18.71)	40.0 (20.48)	0.115 ^b
Gender					
	Male Female		86 (43.9%) 110 (56.1%)	19 (73.1%) 7 (26.9%)	0.005 ^c
Weight ((g)ª		61.7 (13.12)	62.3 (11.30)	0.831 ^b
Height (r	n)ª		1.6 (0.08)	1.6 (0.08)	0.124 ^b
BMI ^a			25.4 (4.76)	24.4 (3.72)	0.519 ^b
Comorbi	dities				
	Diabetes	Yes No	21(10.7%) 175 (89.3%)	4 (15.4%) 22 (84.6%)	0.479 ^c
	Hypertension	Yes No	63 (32.1%) 133 (67.9%)	7 (26.9%) 19 (73.1%)	0.590°
	Malignancy	Yes No	42 (21.4%) 154 (78.6%)	5 (19.2%) 21 (80.6%)	0.797 ^c
	Others	Yes No	50 (25.5%) 146 (74.5%)	7 (26.9%) 19 (73.1%)	0.877 ^c
Type of p	orocedure				
Appendix surgery Others		69 (35.2%) 127 (64.8%)	12 (46.2%) 14 (53.8%)	0.276 ^c	
Wound C	lassification Clean & Clean-cont Contaminated & Di	aminated rty	139 (70.9%) 57 (29.1%)	8 (30.8%) 18 (69.2%)	<0.001°
Nature o	f surgery	Yes	121 (61 7%)	23 (88 5%)	0.007
	Emergency	No	75 (38.3%)	3 (11.5%)	0.007

SSI= Surgical site infection; SD= Standard deviation; BMI= Body mass index

a = Reported in mean (SD); b = Analysed using Independent sample t-test; c = Analysed using Chi-square test

Table 4. Factors associated with SSI (using multiple logistic regression)					
Factor		OR (95% CI)	<i>p</i> -value	AOR (95% CI)	<i>p</i> -value
Gender	Male Female	3.47 (1.40- 8.64) Ref	0.007	2.54 (0.98- 6.55) -	0.054
Wound C	lassification Clean & Clean-contaminated Contaminated & Dirty	Ref 5.49 (2.26- 13.34)	<0.001	- 4.53 (1.82- 11.23)	0.001
Nature of	surgery Emergency Elective	4.75 (1.38- 16.37) Ref	0.014		

OR= Odds ratio; AOR= Adjusted odds ratio; CI= Confidence intervals; Ref= Reference

were detected during the same admission (n=21, 80.8%), while five cases (19.2%) were related to re-admission [*Figure 2*]. Superficial incisional SSI, deep incisional SSI and organ/ space SSI were detected with an incidence of 19.2%, 42.3% and 38.5% respectively [*Figure 3*], with the majority of those detected at day-4 to day-7 post-operatively [*Figure 4*].

Risk factors associated with SSI Univariate analysis showed that three variables were significantly associated with increased risk of SSI; these included: gender (p=0.007), wound classification (p<0.001) and nature of surgery (p=0.014) [Table 3].

The most common risk factors associated with SSI were male gender, with an odds ratio (OR) of being 2.54 times more likely to develop SSI (p=0.054), and surgical wounds classified as contaminated or dirty with an OR of 4.53 of developing SSI compared with clean and clean-contaminated surgical wounds (p<0.001)

Table 5. Secondary procedures of SSI				
SI Re-debridement		dement	Re-suturing	
	OT n (%)	Bedside n (%)	No n (%)	Yes n (%)
Superficial incisional	0 (0.0%)	5 (26.3%)	4 (21.1%)	1 (14.3%)
Deep incisinal	1 (14.3%)	10 (52.6%)	10 (52.6%)	1 (14.3%)
Organ/space	6 (85.7%)	4 (21.1%)	5 (26.3%)	7 (71.4%)
Total	7 (100%)	19 (100%)	19 (100%)	7 (100%)

OT: Operation theatre

Table 6. Microbiology cultures of SSI			
Isolated microorganisms	n (%)		
Escherichia coli	8 (30.8%)		
Klebsiella pneumoniae	4 (15.4%)		
Pseudomonas aeroginosa	3 (11.5%)		
Strep Group D	2 (7.7%)		
Proteus vulgaris	1 (3.8%)		
Proteus mirabilis	1 (3.8%)		
Enterobacter sp.	1 (3.8%)		
Morganella morganii	1 (3.8%)		
Candida spp. Non Albicans	1 (3.8%)		
No growth	4 (15.4%)		

[Table 4]. The data showed that patients who had a emergency procedure were also a higher risk (p=0.007), however, following multivariate logistic regression analysis, this variable was not statistically significant.

Impact of SSI

The mean length of stay (LOS) for patients with an SSI was 20.54 days (SD=12.381). All the confirmed SSI cases underwent secondary procedures, such as, debridement either in the operating theatre (OT) or at the bedside and wound coverage such as re-suturing and split thickness skin grafting. Debridement in the OT and re-suturing were predominantly undertaken for patients with organ/space SSI (n=6 and n=5 respectively) [*Table 5*].

Most common pathogen isolated in SSI Of the total number of cultures (n=26), 22 were positive with the most common isolated pathogens being *Escherichia coli* (n=8, 30.8%), *Klebsiella pneumonia* (n=4, 15.4%) and *Pseudomonas aeroginosa* (n=3, 11.5%) [Table 6].

Summary

Overall the results showed that the SSI incidence was 11.7%. The risk factors associated with SSI were male gender and surgical wounds

classified as contaminated or dirty. In addition, the most common isolated pathogens detected were *Escherichia coli*. All the confirmed SSI cases underwent secondary procedures and contributed to prolonged LOS or re-admission.

Discussion

SSI Incidence

The incidence of SSI in this study was 11.7% which is higher than published figures from India (5%) and Greece (5.3%), however, these studies related to patients undergoing clean procedures (Roumbelaki et al, 2008; Lindsjö et al, 2015). In contrast, the SSI incidence was lower compared to data from Africa, Tanzania and Nepal (16.4%, 26% and 23% respectively) (Mawalla et al, 2011; Giri et al, 2013; Lubega et al, 2017).

A number of authors have identified overcrowding as a factor increasing the risk of SSI and cross-infection (Borg et al, 2008; Assawapalanggool et al, 2016). Overcrowding of patients in hospital is both a local and national issue in Malaysia (Aatif, 2015). In the hospital where the study took place, the bed occupancy rate is always above 100% (unpublished data) and coupled with understaffing is likely to have impacted on the rate of SSI. It was noted that a number of patients presented quite late to the hospital when an infection did develop. This may be in part due to the logistical difficulties of travelling to the hospital.

Appendix surgery accounted for almost half of the total cases of SSI in the study. These findings are in contrast to Fiorio et al (2006) and Jenkins et al (2016), who reported SSI rates in appendectomies of 4.3% and 1.9% respectively. Unplanned surgery, such as having an appendectomy, is known to put patients at a higher risk of developing an SSI (Akhter et al, 2016). Furthermore, a number of authors have determined that emergency procedures placed individuals at risk of developing an SSI (Malone et al, 2002; Isik et al, 2015). This may be due to a number of factors, including inadequate preoperative preparation, poor control of comorbidities and relatively higher frequency of contaminated and dirty wounds in emergency procedures (Akhter et al, 2016). However, the current study did not find a statistically significant difference in relation to emergency procedures and risk of SSI. This might be explained by the small sample size therefore it is difficult to draw firm conclusions about this aspect.

In this study, there was a slightly higher number of female patients than male patients. The slight imbalance between the genders might be due to the small sample size and the nature of the disease the patients presented with may also be influenced by gender. For example, gallbladder disease and thyroid and/or parathyroid diseases are more common in female patients (Shaffer, 2006; Bures et al, 2014). Despite there being more female patients, male gender was found to be a risk factor associated with SSI in this study. A number of existing studies also showed that male gender may be a higher risk of an SSI (Kim et al, 2012; Nanashima et al, 2014). However, Linsjö et al (2015), identified that female patients were 2.18 times at risk of developing an SSI. These contradictory findings might be procedurespecific. For example, existing evidence has indicated that female gender was a risk factor for SSI in bypass graft surgery, whilst males were more at risk in colorectal and hepatobiliary surgery (Kingston et al, 1995; Vuorisalo et al, 1998; Alp et al, 2014). These contrasting results suggest that further evaluation of the impact of gender on SSI is needed.

The current study also confirmed a statistically significant association between contaminated or dirty wounds and SSI, a finding which is in concordance with previous studies (Dierssen et al, 1996; Malone et al, 2002; Pathak et al, 2014). In the current study, gross spillage from gastrointestinal tract and perforated viscus were considered to be the main reason leading to contaminated and dirty surgical wounds.

Whilst previous studies have shown that diabetes is a risk factor for SSI the current study did not identify such an association. This was unexpected as Malaysia is one of the top ten countries for diabetes prevalence (Shaw et al, 2010). Hyperglycaemia (in the absence of diabetes) is associated with increased risk of SSI (Kwon et al, 2013; Takesue and Tsuchida, 2017), therefore, future studies should take into account blood glucose levels in addition to the presence of diabetes

In this study, the most common organism isolated from the wound cultures was *Escherichia coli*, which is consistent with previous studies (Kasatpibal et al, 2005; Isik et al, 2015). These Gram-negative bacteria could be due to the common flora in the gastrointestinal system and may be indicating inadequate infection control measures and postoperative wound management (Namiduru et al, 2013).

Impact of SSI

Secondary procedures were performed for all SSI cases. Local practice in the hospital where the study took place is to undertake sharp debridement at the bedside due to limited availability of OT time. Surgical wound debridement performed in OT is usually reserved for organ/space SSI which are more complicated. The majority of wounds in patients with SSI were left open to heal by secondary intention. Five cases of organ/space SSI were resutured to prevent prolonged duration of open abdomen.

The mean LOS for patients with a confirmed SSI was 20.54 days. This was less than the 26.6 days reported by Roumbelaki et al (2008) and 25.4 days by Ballus et al (2015). It is wellrecognised that prolonged hospital stay increases hospital costs and also puts the patient at risk of other HAIs such as pneumonia and psychosocial issues such as delirium, psychosis or depression (Werarak et al, 2010; Zielińska and Durlik, 2014; Ballus et al, 2015).

The re-admission rate related to SSI in this study was 19.2% which is almost the same as the findings of Merkow et al (2015) (19.5%). Due to the bed shortages at SGH, patients are often discharged early, which might also contribute to the re-admission rate.

Evaluation of the study

This was the first SSI surveillance study to be undertaken in the local area therefore this provides some baseline data for future audits.

Table 7. Recommendations to reduce the risk of SSI			
Targeted healthcare personnel	Recommendation	Area for improvement	
Public health	Healthcare brochure in different language and dialects targeting rural populations.	Provide and increase usage of screening/ preventive program instead of emergency services. Prevent late presentation of illness. Health care education to increase public health literacy.	
Anaesthetic department	Prioritize emergency cases more vigilantly.	Reduce operation theatre traffic	
Hospital administrator	Well equipped facilities to overcome high demand of patients. Allocate resources and personnel for surveillance.	Provide facilities and manpower.	
Junior medical officers, registrars or trainees	Knowing own limitation and ask- ing for help instantly whenever required.	Prevent prolonged surgery due to lack of operating skills and soft tissue handling.	
Surgeons	To determined whether delayed primary closure is acceptable as routine practice in the department. Early referral to wound care services for difficult surgical wounds.	To formulate local guidelines when deal- ing with contaminated and dirty surgical wounds peri-operatively.	
Infection control staff	Feedback of surveillance to sur- geons and healthcare workers. Periodical surveillance.	Routine audit and surveillance to maintain the healthcare personnel's awareness. Analysis of audit/surveillance data and provide feedback to surgeons and hospital administrators.	
Wound care team	To assist surgeon in managing difficult surgical wounds.	To engage with ward nurses to identify patient at risk of SSI. To provide adequate advice for wound management.	

The limitations of the study were short study period resulting in a small sample size, excluding procedures that fell into the 90-day surveillance period. Furthermore, variables related to pre-operative preparation, surgeon, details of operation, OT environment, antibiotics and anaesthesia factors were not included. Underreporting of SSI due to logistical issues associated with patients attending the hospital may also be a limitation.

However, its strengths were the prospective approach which included all procedures, either emergency or elective, which fell into the 30-day surveillance period. This was the first 30-day SSI surveillance study, which provided data on incidence, associated risk factors and outcomes for both emergency and elective types of procedures. The prospective approach of this study enabled a more rigorous approach to the data collection procedure where, any queries or missed data were able to be clarified immediately. There were a number of recommendations arising from this study including undertaking a longer duration of follow-up to include procedures that fall into 90-day surveillance and to collaborate with the

district healthcare institutes to continue postdischarge surveillance.

Recommendations to reduce the risk of SSI Surgical wounds classed as contaminated or dirty require prompt action to reduce the risk of contamination at the time of operation (Farthmann and Schöffel, 1990). Previous evidence has showed that delayed primary closure (DPC) is an optimal management strategy for contaminated and dirty wounds (Cohn et al, 2001; Chiang et al, 2012). Based on the SSI rate identified in this study there needs to be a review of the use of DPC to determine whether it will be acceptable to be considered as routine practice in this department as it was felt that in some cases this may have been a more appropriate approach for some patients. Furthermore, patients with difficult surgical wounds should be referred to the wound care service sooner, as recommended in the National Institute for Health and Care Excellence (NICE, 2019) clinical guidelines to reduce the impact of SSI. In addition, the wound care team in the hospital could be more proactive in terms of engagement with the ward nurses to identify

patients at risk or demonstrating signs and symptoms of SSI. At a governmental level the public health sector should reinforce public health education to reduce the late presentation of illness which lead to contaminated or dirty surgical wounds. Healthcare campaigns and screening could be promoted more frequently in rural areas, healthcare leaflets should not be limited to Malay and English languages but the dialects of indigenous populations in Sarawak. It is intended to undertake a quality improvement project with recommendations suggested in *Table 7.* Re-audit after the implementation of the recommendations is hoped to show reduced SSI incidence in this hospital.

Conclusions

The results of this study identified that the SSI incidence in the General Surgery Department at SGH over the two-month period of the main study was 11.7%. In this study, being male and having a wound classed as contaminated or dirty surgical were shown to be associated with SSI development. However, being diabetic and having an emergency procedure did not demonstrate an association with risk of SSI. This could be due to the short duration of the study which involved only small sample size and was thus unable to detect all the significant findings.

It is acknowledged that eradication of SSI is almost impossible (Medeiros et al, 2005), thus, the aim should be to reduce the incidence of SSI. Currently in Malaysia, there are no standard local guidelines for the prevention of SSI. However, international guidelines are available, for example, the CDC Guideline for Prevention of Surgical Site Infection and recommendations from the World Health Organization (Mangram et al, 1999; Allegranzi et al, 2016; World Health, 2018). Therefore, it is suggested that at a national level the Ministry of Health in Malaysia should implement local regulations as well as introducing a system of mandatory surveillance. In the meantime, the findings of the current study can serve as initial evidence WAS for the burden of SSI.

Acknowledgements

The authors would like to thank the Director General of Health Malaysia for his permission to publish this article.

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