抗菌縫線與手術病患安全

衛福部 疾病管制署 中區傳染病防治醫療網 王任賢 指揮官

Outline

- The global definition of SSI & TW current status
- Risk factors of SSI
- HE Clinical evidence of SSI prevention

US CDC Report



- In the US, at least 780,000 SSIs occur each year¹
- SSIs account for about 37% of all hospital-acquired infections for surgical patients 1
- SSIs occur in up to 5% of surgical patients²
- SSIs are the 2nd most common nosocominal HAI (hospital-associated infection).3



- WHO Guidelines for Sofe Surgery 2009.
 Cheadle WG. Risk factors for surgical site infection. Surg Infect. 2006;7: s7-s11.
 Mangram A, et al, CDC guideline for prevention of surgical site infection. Infection Control & Hospital Epideminology, 1999;20(4):247-280

Taiwan CDC report

- In Taiwan, SSIs account for approximately 4 15% of all HAIs.1-3
- Overall incidence of SSI between 1 15%.^{2,4-6}
- Rate of SSI vary substantially according to:
 - Surgical procedure
 - Surveillance period (pre- and/or post-discharge)
 - Wound classification
- National Nosocomial Infections Surveillance System Report, 2006
 S. Sheng WH et al. J Hops Infect 2005;99[3]:205-214.
 Sheng WH et al. J Forms Med Assoc 2007;106[2]:110-118.
 Chen YY et al. Infect Control Hops Epidemiol 2009;30[1]:39-46.
 S. Maa SH et al. Infect Control Hops Epidemiol 2008;29(8):767-770.
 Su BH et al. Am J Infect Control 2007;35(3):190-195.

AP region SSI by procedure Inguinal hernioplasty (Malaysia) Neurosurgery (Vietnam) Organ/space 1. Park C et al. Transplantation 2009;87(7):1031-1036. 2. Praveen S et al. Axian J Surg 2009;32(1):59-63. 4. Thu LTA et al. Infect Control Hosp Epidemiol 2006;27(8):855-862. 5. Selandindawat P et al. J Med Asocc Thai 2007;90(7):1356-1362. 6. Thu LTA et al. Infect Control Hosp Epidemiol 2006;27(8):855-862. 6. Tang K et al. J Arthroplasty 2001;16(1):102-106. 6. Tang K et al. J Arthroplasty 2001;16(1):102-106.

Incidence of SSI in CVS & GS

- Cardiothoracic and vascular surgery: 2.9 7.1%
- Gastrointestinal tract surgery: 1.4 48.3%

Source	Surgical procedure	Surveillance period	Incidence (%)	
Cardiothoracic	and vascular			
	CABG	Pre-discharge	3.3% (106/3227)	
Wu 2006 ¹		30 days post-discharge	5.6% (179/3227)	
Pan 2000 ²	Open heart surgery	At least 4 weeks post-operation	2.9% (43/1491)	
	Cardiac surgery (sternal SSI)	30 days post-operation	5.1% (24/471)	
Ku 2005 ³	CABG (leg SSI)	Not reported	7.1% (23/323)	
Gastrointestino	al tract			
Chuang 2004 ⁴	Open Cholecystectomy		14.4% (18/125)	
Citualig 2004*	ng 2004 ⁴ 30 days post-operation Laparoscopic cholecystectomy	su days post-operation	1.4% (6/420)	
Liu 2007 ⁵	Appendectomy for perforated appendicitis	Not reported	27.3% (33/121)	
Shan 2003 ⁶	Gastric surgery	Pre-discharge	48.3% (70/145)	

27(3):308-311. 2. Pan SC et al. Formosan J Surg 2000;33(6):281-286. 4. Chuang SC et al. J Formos Med Assoc 2004;103(8):607-612. 6. Shan YS et al. Br J Surg 2003;90(10):1215-1219.

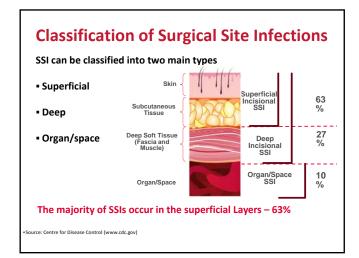
Incidence of SSI in Orthopaedic surgery

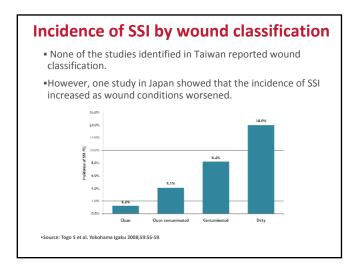
- Orthopaedic surgery: 1.8 4.9%
- Other surgical procedures: 4.7 24.5%

Source	Surgical procedure	Surveillance period	Incidence (%)
Orthopaedic su	rgery		
Chang 2010 ¹	Total hip or knee replacement	Pre-discharge or re-admitted within 30 days post-operation	1.8% (56/3081)
Liu PC 2008 ²	Open reduction and internal fixation	At least 6 months post-operation	4.9% (7/142)
		Spinal surgery At least 4 weeks post-operation	
Kuo 2004 ³	Spinal surgery	At least 4 weeks post-operation	2.2% (72/3230)
Kuo 2004 ³ Other surgical p		At least 4 weeks post-operation	2.2% (72/3230)
		At least 4 weeks post-operation Pre-discharge	2.2% (72/3230) 19.8% (197/997)
Other surgical p	procedures		

Definition Surgical Site Infection

- The US Centre for Disease Control (CDC) defines surgical site infection (SSI) as:
 - •An infection that occurs at an incision site, or any part of the anatomy that was opened or manipulated during the procedure.
 - An infection that occurs within 30 days after surgery, or within 1 year in the presence of an implant.





Mortality risk to patients with SSIs

- A patient with an SSI is:
- 5x more likely to be readmitted after discharge¹
- 2x more likely to spend time in intensive care¹
- 2x more likely to die after surgery1
- The mortality risk is higher when SSI is due to MRSA
- A patient with MRSA is 12x more likely to die after surgery²

WHO Guidelines for Safe Surgery 2009.
 Engemann JJ et al. Clin Infect Dis. 2003;36:592-598.

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SSIs Financial burden on the healthcare system in US

- The average cost of treating one SSI is between \$11,000 and \$35,0001
- The average cost of treating one MRSA-related SSI is more than \$60,000²
- In total, SSIs have been estimated to cost the US healthcare system up to \$10 billion/yr¹

L. Scott RD. Centers for Disease Control and Prevention. March 2009.

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SSIs Financial burden on the healthcare system in Taiwan

TKR	SSI Type	Incidence Rate	Avg Medical cost Per Patient	Avg. Length of Hospit al stay	readmitted Rate	Mortality Rate
73,475pt	No SSI		NT\$135,802	9 days		
	Superfical SSI	2.33% (2.14%~2.65%)	NT\$137,413 (+ NT\$1,611)	Not reported	3.29% (2.95%~3.68%)	Not reported
	Deep SSI	1.32% (0.84%~1.64%)	NT\$173,249 (+ NT\$37,447)	27 days		0.01%
THR	SSI Type	Incidence Rate	Avg Medical cost Per Patient	Avg. Length of Hospit al stay	readmitted Rate	Mortality Rate
75,547 pt	No SSI		NT\$108,886	11 days		
	Superfical SSI	2.92% (2.88%~2.95%)	NT\$128,029 (+ NT\$ 19,143)	Not reported	8.22%	Not reported
	Deep SSI	2.18% (1.48%~2.74%)	NT\$186,069 (+ NT\$77,182)	29 days	(7.62%~8.56%)	0.04%

^{**} medical cost is excluded patient self-pay items

- 2010 CDC DATA
- ・ Web date:http://www.nhi.gov.tw/行政院衛生署全民庭康中與庭康保護局.諮疫西南省市福軍

Economic burden of SSI in Taiwan

- Extended hospital stay associated with SSI
 - Hospital stay: Additional 14 days
 - ■ICU stay: 1 10 additional days

Source	Surgery type	Type of stay	Mean length of stay (days)		
Source	Surgery type	туре от заау	No SSI	SSI	Difference
Ku 2005¹	Cardiac surgery - sternotomy	ICU	53.9 hours ± 38.1	78.3 hours ± 48.4	~24 hours *
Ku 2005*	Cardiac surgery- saphenous vein graft	ICU	53.9 hours ± 38.1	79.1 hours ± 76.4	~25 hours *
Sheng 2005 ²	All inpatients (medical centre)	ICU & Ward	Not reported		14.4 days ± 25.8
Siletig 2005	All inpatients (community hospital)	ICU & Ward	Not reported		14.4 days ± 9.6
Wang 2000 ³	CABG (deep sternal wound infections)	ICU	4.9 days ± 5.85	14.9 days ±14.09	~10 days *
Wang 2000 ³	,				

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- Risk factors of SSI
- HE Clinical evidence of Antibacterial suture

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Factors in Bacterial Colonization Leading to SSIs

Patient-related

Procedure/Techniques

Wound classification

Implants



*Hebert CK et al. Clin Orthop. 1996;331:140-145.
*Fletcher N et al. J Bone Joint Surg Am. 2007;89:1605-1618.
*Mangram AJ et al. Am J Infect Control. 1999;27:97-134.
*Fry DE. Medscape Surgery. 2003.

Who is at Risk of a SSI? Patient Characteristics

- Age
- Diabetes
 - HbA1C and SSI
 - •Glucose > 200 mg/dL postoperative period (<48 hrs)
- Nicotine use
 - •delays primary wound healing
- Steroid use:
- Controversial
- Malnutrition:
 - •no epidemiological association
- Obesity:
 - •20% over ideal body weight

- Prolonged preoperative stay:
 - surrogate of the severity of illness and comorbid conditions
- Preoperative nares colonization with Staphylococcus aureus:
 - significant association
- Perioperative transfusion:
- •controversial
- Coexistent infections at a remote body site
- Altered immune response
- Mangram et al. Infect Control Hosp Epidemiol. 1999;20:247-277.

Who is at Risk of a SSI? Operative Factors

- Duration of surgical scrub
- Maintain body temp
- Skin antisepsis
- Preoperative shaving
- Duration of operation
- Antimicrobial prophylaxis
- Operating room ventilation
- Inadequate sterilization of instruments
- Foreign material at surgical site
- Surgical drains
- Surgical technique
 - Poor hemostasis
 - Failure to obliterate dead space
 - •Tissue trauma

Mangram et al. Infect Control Hosp Epidemiol. 1999;20:247-277.

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Who is at Risk of a SSI? Wound classification

Wounds are generally classified into four categories:1

- •Class 1 = Clean
- •Class 2 = Clean contaminated
- Class 3 = Contaminated
- Class 4 = Dirty infected

NNIS project found that there are three independent variables associated

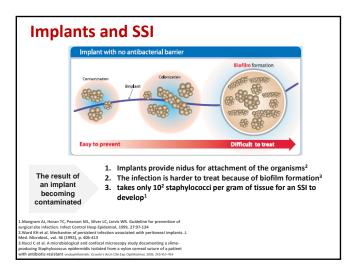
- Contaminated or dirty/infected wound classification
- •Length of operation > 75th percentile of the specific operation being performed
- Mangram et al. Infect Control Hosp Epidemiol. 1999;20:247-277.
 NNIS. CDC. Am J Infect Control. 2001;29:404-421.

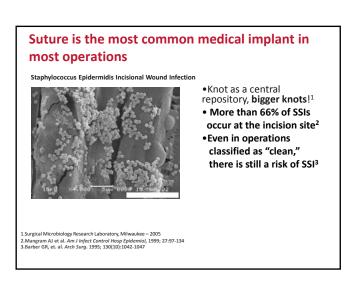
Patient-associated risk factors identified in Taiwan Risk variable Surgical procedure specified Risk estimate (95% CI) P value Source Chuang 2004¹ Poorly controlled diabetes Cholecystectomy Wu 2006² OR 2.02 (1.19, 3.42) Diabetic 0.0099 Liu S-A 2006³ Diabetes mellitus Head and neck surgery OR2.51 (1.41, 4.48) 0.002 Age Ku 2005⁴ Saphenous vein harvest (leg) OR 1.09 (1.01, 1.17) 0.029 OR 1.14 (1.05, 1.23) Ku 2005⁴ Age (years) Sternotomy 0.002 Gastrointestinal OR 3.15 (1.41, 6.92) Shan 2003⁵ Age ≥60 years 1. Chuang SC et al. J Formos Med Assoc 2004;103(8):607-612. 3. Liu SA et al. Laryngoscope 2007: 117:166-171. 5. Shan YS et al. Br J Surg 2003;90(10):1215-1219 2. Wu SC et al. Infect Control Hosp Epidemiol 2006;27(3):308-311 4. Ku CH et al. Am J Epidemiol 2005;161(7):661-671.

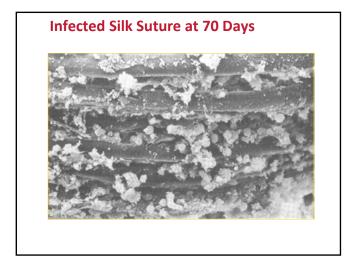
SSI Risk according to Operative procedure: NNIS, 1992 to 2004 NNIS = National Nosocomial Infection Surveillance; GAST=gastric; FUSN=spinal fusion; CABG=chest and donor site; VSHN=ventricular shunt; HYST=abdominal hysterectomy; APPY=appendectomy; XLAP=laparctomy; TP=organ transplant; HER=hemiorrhaphy; VS=vascular NNIS System. National Nosocomial Infections Surveillance System Report, data summary from Japuary 1992 through June 2004, issued October 2004. Am J Infect Control. 2004;32:470-485.

Who should receive prophylaxis? > Surgical procedures with a high rate of wound infection ➤ Clean-contaminated, contaminated Remember dirty cases receive therapeutic not empiric antibiotics > Implantation of prosthetic materials Surgical procedures where infection would have severe consequences 1. Platt et al. NEJM 1990; 322:153-160.





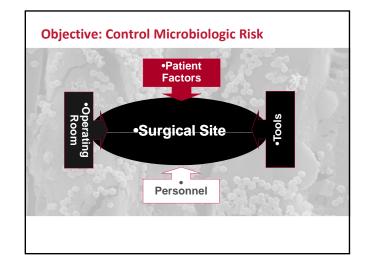


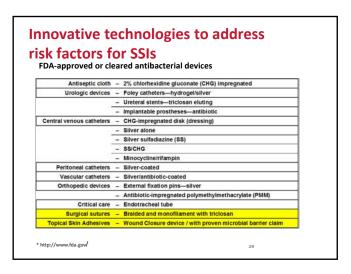


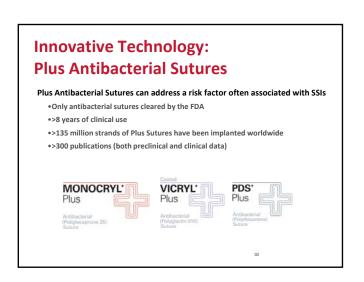
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Plus Antibacterial Sutures: Protection against bacterial colonization

Plus SUTURES are designed to reduce a risk factor for SSIs by preventing bacterial colonization of the suture^{1,2}

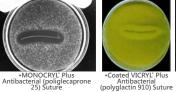
- •Plus Sutures contain IRGACARE® MP (the purest form of triclosan)
- •IRGACARE® MP actively inhibits colonization of the suture by pathogens commonly associated with SSIs, including:1,3,4
- •Staphylococcus aureus
- •Staphylococcus epidermidis
- MRSA
- •MRSE
- Escherichia coli
- •Klebsiella pneumoniae

- Rothenburger et al. Surg Infect. 2002;3:79-87.
 Mangram AJ et al. Infect Control Hosp Epidemiol.1999;27:97-134.
 Ming x, Nichols M, Rothenburger S. Surg Infect. 2007;8:209-213.
 Ming X, Rothenburger S, Nichols MM. Surg Infect. 2008;9:451-457.

Plus Antibacterial Sutures: Protection against bacterial colonization

Plus SUTURES have been proven in vitro to create a zone of inhibition against the most common surgical site pathogens:1-3







- 2.
- Storch ML, Rothenburger SJ, Jacinto G. Experimental efficacy study of coated VICRYL plus antibacterial suture in guinea pigs challenged with Staphylococcus aureus. Surg Infect. 2004;5:281-288 Ming X, et.al. in vivo antibacterial efficacy of MONOCRYL plus antibacterial suture (poliglecaprone 25 with triclosan). Surg Infect. 2007;8:209-213 Ming X, et.a. In vivo and in vitro antibacterial efficacy of PDS* plus (polidioxanone 25 with triglosan) suture. Surg Infect. 2008;9:451-457

Efficacy test of Coated VICRYL PLUS in MRSA





Tested and Photo Taken by Korea University Graduate School of Life Sciences Lab September 2007

Characteristics of Silk

1) Braided

- Bacteria is likely to adhere.



2) Extremely Hydrophilic

- To provide an easy-to-live environment for bacteria, where bacteria rapidly multiply. (Bacteria need water to grow) However Synthetic Absorbable have ow hydrophilic, bacteria are unlikely to



3) Natural Animal Protein

Since silk sutures are natural animal protein, the living body recognizes them as apparent enemies and starts attacking them.

(Since a virus is also a foreign protein, autoimmune cells attacks the virus)

4) Permanent Foreign Body in the Body

Silk sutures remaining in the body are permanently recognized as foreign bodies at cellular level. (Foreign

remain in the body as foreign body.

HE Clinical Evidence

Impact of using triclosan-antibacterial sutures on incidence of surgical site infection

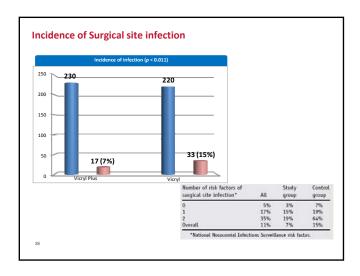
Ibrahim Galal, M.D.a,*, Khaled El-Hindawy, M.D.b

- Publication: The American Journal of Surgery (2011) 202,133-138
- Method: prospective, randomized, double-blinded, controlled multiple center study

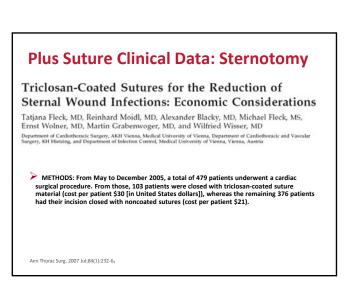
Background

Study design:

- Study Group: 230 patients triclosan-coated polyglactin 910 antimicrobial sutures (Vicryl Plus) were used in all surgical steps except in some cases polypropylene was used for laparotomy closure and vascular suture
- Controlled Group: 220 patients conventional polyglactin 910 sutures (Vicryl) were used in all surgical steps except in some cases polypropylene was used for laparotomy closure and vascular suture, and Poliglecaprone 25 was used in skin closure.



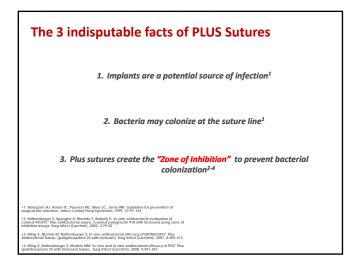
Results Table 7 Total cost per patient with or without surgical site infection Number of patients Surgical site infection Number of patients 50 Heave length of hospital stay 7.10 13.99 Daily cost 1E 180 (533) in first 3.39 days and LE 500 (591) in the 1E 180 (533) Total cost per patient • Surgical site infections occurred in 17 of 230 patients (7%) in the study group versus 33 of 220 (15%) in the control group • The mean extended stay in this study was 3.71 days. • Per patient total cost is USD 448 in SSI group vs USD 112 in non-SSI group • The impact on health care resources by the extra occupation of hospital beds could reach 16,695 bed-days annually. • If these bed-days could be saved, this could increase the capacity by 4,925 surgical cases per year

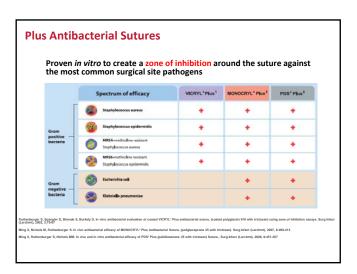


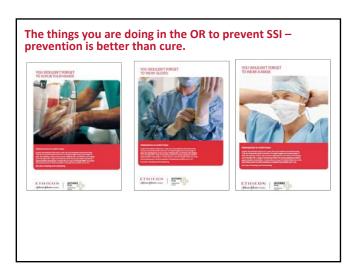
RESULTS: During the study period, 24 patients had superficial (n = 10) or deep (n = 14) sternal wound infections (cost per patient \$11,200). All those patients were closed with conventional suture material. In the triclosan group, no wound infection or dehiscence was observed during hospital stay and follow-up visits. **SSI Medical Extra Cost USD 11,200 / PATIENT** **Antibacterial Suture Extra cost Only USD \$ 9/PATIENT** **Only USD \$ 9/PATIENT**

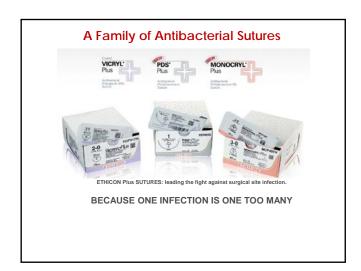
Conclusions >: Triclosan-coated sutures might be valuable in the reduction of sternal wound infections and avoid the suture being a risk factor for surgical site infections. The increased cost of the coated suture material has to be weighed against the enormous cost of sternal wound infections caused directly by the cost of care as well as indirectly through the loss of economic productivity.

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Procedure	Recommeded Suture	FAB
Gastrojejunostomy	4-0 Aantibaterial PDS Suture	Inhibit MRSA, MRSE,SA,SE,E.Col & K.P. 180 days aborption
	3-0 Antibaterial MONOCRYL Suture	Inhibit MRSA, MRSE,SA,SE,E.Coli & K.P.
Hepaticojejunostomy	5-0 Antibaterial PDS Suture with DBLE ARMED	Inhibit MRSA, MRSE,SA,SE,E.Coli & K.P. Easy to handle
	5-0 PROLENE Suture with DBLE ARMED CC needle	decidecated for anastomosis procedure
Colon anastomosis	Outer Layer 3-0 Antibaterial VICRYL Suture C/R	MRSA, MRSE,SA,SE time saving
	<u>Inner Layer</u> 4-0 Antibaterial PDS Suture	MRSA, MRSE,SA,SE,E.Coli & K.P.

