EBreast II

Aseptic safety in breast patient care
Part 1

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Introduction

- This presentation is the first of two presentations focusing on enabling safe breast cancer patients' pathway from the Surgical Site Infection (SSI) prevention and control points of view.
- This first part introduces the main concepts in the microbiological safety, the overall, patient, and procedure related risks to SSIs in breast surgery.
- The second part discusses critical aseptic incidents, crucial for all the professionals working in the breast cancer patients' pathway.
- In part two, The Aseptic Practices in Breast Surgery –model serves as a structure for the practical implementation of the infection prevention and control measures in the breast patients' pathway.

Learning outcomes

After the two presentations, the learner is able to demonstrate

1) Critical knowledge of aseptic safety in breast surgery patient care.

2) Ability to implement patient and procedure specific infection prevention and control measures in breast surgery patient care.

3) Ability to guide the breast surgery patient and personnel to prevent, follow-up, and report surgical site infection related outcomes.

EBreast II

Background

The breast cancer patients in this project, expected to have comprehensive and timely guidance and information related to their upcoming breast cancer pathway enabling them to prepare themselves “for what was to follow” (1).

The patients mentioned the outcomes of the breast surgery as positive experiences after their surgical procedures, and lack of follow-ups as negative experiences (1).

The health care professionals defined the competency of health care personnel performing surgery, trust on health care professionals, and clear information given to the patient of different aspects of surgery, the key factors related to a successful breast cancer pathway (2).

According to the EUSOMA, the breast patient’s preoperative part of the care pathway consists of several hospital visits, discussions with multidisciplinary team members, and nurse counselling for diagnostic and surgical procedures (3, 4).

Introduction..

- Our retrospective patient chart survey revealed breaks in patients' pathways, particularly in infection prevention and control (IPC) documentation, follow-up and feedback (5).

- From the IPC points of view, the ability to argue patient information with evidence-based knowledge and the awareness of the cancer patient's whole perioperative process are key competencies in safe surgery performed by all professionals working on the pathway.(6,7).

- The critical use of local IPC data collected by hospital infection surveillance systems or professionals is important due to the biases in the local pathways, circumstances and resources. It is important to prevent the biases by structured follow-up measures.(5-9).

Definitions by The EU COUNCIL

- ‘Adverse event’ is an incident which results in harm to a patient.
- ‘Harm’ implies impairment of the structure or function of the body and/or any deleterious effect arising therefrom.
- ‘Healthcare associated infection’ (HAI) means diseases or pathologies related to the presence of an infectious agent or its products in association with exposure to healthcare facilities or healthcare procedures or treatments.
- ‘Patient safety’ means freedom, for a patient, from unnecessary harm or potential harm associated with healthcare.
- ‘Process indicator’ means an indicator referring to the compliance with agreed activities such as hand hygiene, infection surveillance, standard operating procedures (SOP).
- Structure indicator’ means an indicator referring to any resource, such as staff, an infrastructure, or a committee.

(10)

Healthcare-associated infections (HAI) as a threat to patient safety

According to The European Disease Control and Prevention (ECDC):

"Healthcare-associated infections are infections acquired by patients during their stay in a hospital or another healthcare setting. Although some of these infections can be treated easily, others may more seriously affect a patient's health, increasing their stay in the hospital and hospital costs, and causing considerable distress to these patients."

- The most frequently reported types of healthcare-associated infections are:
  - Respiratory tract infections,
  - Surgical site infections (SSI),
  - Bloodstream infections and
  - Gastro-intestinal infections. (11)

Definitions for SSI by ECDC

Superficial incisional infection:

Infection occurs within 30 days after the operation involving only skin and subcutaneous tissue of the incision and at least one of the following:
· purulent drainage with or without laboratory confirmation, from the superficial incision
· organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
· at least one of the following signs or symptoms of infection: pain or tenderness, localised swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative
· diagnosis of superficial incisional SSI made by a surgeon or attending physician.

Deep incisional infection:

Infection occurs within 30 days after the operation if no implant is left in place or within 90 days if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissue (e.g. fascia, muscle) of the incision and at least one of the following:
· purulent drainage from the deep incision but not from the organ/space component of the surgical site
· a deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (> 38°C), localised pain or tenderness, unless incision is culture-negative
· an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
· diagnosis of deep incisional SSI made by a surgeon or attending physician.

Organ/space infection:

Infection occurs within 30 days after the operation if no implant is left in place or within 90 days if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g. organs and spaces) other than the incision that was opened or manipulated during an operation and at least one of the following:
· purulent drainage from a drain that is placed through a stab wound into the organ/space
· organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
· an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
· diagnosis of organ/space SSI made by a surgeon or attending physician.

Risk Factors for surgical site infections

According to ECDC, in European countries the patient's SSI risk index is the index used in the US National Healthcare Safety Network (NHSN) and assigns the surgical patients into categories based on the presence of three major risk factors 1) Wound contamination class, 2) ASA classification by American Society of Anaesthesiologists, and 3) Duration of operation. (11 -13)

Calculation	Score =0, if	Score=1, if:
Wound contamination class	W1, W2	W3, W4
ASA classification	A1, A2	A3, A4, A5
Duration of operation under 75th percentile cut-off value in hours	≤ 75th percentile cut-off value in hours	> 75th percentile cut-off value in hours
Basic SSI risk index	= Sum of scores	Max 3= Sum of scores

(11)

Wound contamination class	Description
W1	**A clean wound** is an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow non-penetrating trauma should be included in this category.
W2	**Clean-contaminated wounds** are operative wounds in which the respiratory, alimentary, genital or uninfected urinary tracts are entered under controlled condition and without unusual contamination. Specifically operations involving the biliary tract, appendix, vagina and oropharynx are included in this category provided no evidence of infection or major break in technique is encountered.
W3	**Contaminated wounds** include open, fresh, accidental wounds. In addition operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.
W4	**Dirty or infected wounds** include old traumatic wounds with retained devitalised tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

(11-13)

Generic risk factors for SSI

In addition to the classical SSI risks also more detailed procedure and patient specific risks have been reported in several studies.

Patient related risk factors for surgical site infections
Age
Male gender
Nutritional status
Diabetes
Smoking
Obesity
Coexistent infections at a remote body site
Colonization with microorganisms
Altered immune response
Length of preoperative stay in hospital
Medication
Hypothermia
Reduced blood flow following hemorrhage
Reduced subcutaneous perfusion and oxygenation
Operation related risk factors for surgical site infections
Preoperative skin preparations
Preoperative shaving
Skin antisepsis
Duration of surgical scrub
Duration of operation
Antimicrobial prophylaxis
Operating room ventilation
Inadequate sterilization of instruments
Foreign material in the surgical site
Surgical drains
Surgical technique
Poor hemostasis
Failure to obliterate dead space
Tissue trauma
Emergency of the operation
OT traffic

*Modified from Haley et al. 1985a; Haley 1991; Chaudry & Ayala 1992; Hyrylä 1993; Hopf et al. 1997; Kamph et al. 1997; Mangram et al. 1999; Safdar et al. 2003; Moro et al. 2005; Palma et al. 2006; Rioux et al. 2006 & 2007; Gordon et al. 2009; Couris et al. 2007; Alexander et al. 2011; Beltramini et al. 2011; Berríos-Torres et al. 2017.

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SSI in breast surgery

- “Breast operations” cover a variety of surgical procedures from local excisions to mastectomies without or with immediate or delayed reconstructions each having patient and procedure specific consequences to breast operated patients, particularly SSIs (14).

- The SSI risk index makes the risks related outcomes clearly visible. After mastectomies, the SSI rates reported as 2.07% in risk index category 0 & 1, and 3.97% in risk index category 2 & 3 respective (15).

- In large scale breast surgery outcome studies the expected SSI rates in these “clean surgery” operations reported between 2% and 4%. (9,16,17).

- In the US, the SSI rates in breast surgery are traditionally reported varying from 1 % to 2%. The rates are lower than in Europe or elsewhere outside the US varying for example from 0% (8) near to 20% (18). This may be due to weaknesses in postoperative follow-up, quality problems in perioperative care or variation in the patient and procedure related risks. (6).

Surgical site infection rates and risks in breast operations.

Type and number (N) of operations	SSI rate (%)	Risks, operation and follow-up characteristics	Reference
Mastectomy (N=9,486) (N=665)	1.7 5.0	Risk index 0,1 Risk index 2,3 Duration cut point 2 h	NNIS system October 1986 – April1998 NNIS 1999 (US)
Mastectomy (N=11,178) (N=403)	2.1 4.0	Risk index 0,1 Risk index 2,3 Duration cut point 3 h	NNIS system January 1990 – May 1999 NNIS 1999 (US)
Mastectomy (N=13,623) (N=8,509) (N=635)	1.9 2.3 3.4	Risk index 0 Risk index 1 Risk index 2,3 Duration cut point 3 h	NNIS system January 1992 – June 2002 NNIS 2002 (US)
Mastectomy (N=16,287) (N=10,700) (N=1,112)	1.8 2.2 3.4	Risk index 0 Risk index 1 Risk index 2-3 Duration cut point 3 h	NNIS 2004 January 1992 – June 2004 NNIS 2004 (US
Mastectomy (N=311)	1.9 3.0	NNIS risk index 0-1 NNIS risk index 2-3	Moro et al. 2005 (Italy)
Mastectomy (N=7449)	1 -1.7	4-year surveillance	Brandt et al. 2006 (Germany)
Breast operations (N=1,338) PDS completed (n=1,122) No PDS completed (n=216) (n=752) (n=104) (n=174) (n=27)	 8.9 0.9 7.4 0 18.4 3.7	 NNIS risk 0, PDS NNIS risk 0, no PDS NNIS risk ≥1, PDS NNIS risk ≥1, no PDS	Reilly et al. 2006 (UK)
Mastectomy / mammary tumorectomy (n=2,438)	2.7		Rioux et al. 2007 (France)
Breast operations (N=949) Mastectomy + implant Mastectomy + reconstruction Mastectomy only Breast reduction	 12.4 6.2 4.4 1.1	 Risks: DM, BMI > 30, implant, central venous catheter	Olsen et al. 2008 (US)
Breast cancer operations (N=2,338)	18.9	Risks: chemo radiation, hematoma, BMI >30 Duration cut point > 3h	Villar-Compte et al. 2009 (Mexico)
Breast cancer operations (N=199)	19.1	Risks: high BMI, DM, smoking, skin disorder, tumour at high stage, neoadjuvant therapy	Angarita et al. 2011 (Columbia)
Breast reconstructions (N=297)	7.7	Risks: high BMI; DM	Adetayo et al. 2012 (US)
Breast operations (N=26,988) Mastectomy (n=10,471) Lumpectomy (n=16,517)	5.6 4.0 1.6	High BMI, Smoking, DM, previous re-operation	de Blacam et al. 2012 (US)
Mastectomy no reconstruction (N=38,739)	2.3	Risks: BMI >25; ASA ≥3; DM; operation time> 75th percentile (> 2 h), smoking	Davis et al. 2013 (US)
Breast-conserving operations Primary operation (n=23,001) Re-operation (n=5,826)	 1.8 2.4	 90 day SSI rate	Olsen et al. 2015 (US)
Breast operations (N=72,058) Mastectomy (n=3,447) Mastectomy + flap (n=4,065) Mastectomy + implant (n=18,300)	3.6 2.3 4.8 5.1	90 day SSI-rate	Saeed et al. 2015 (US)

BMI= body mass index; DM = Diabetes Mellitus; PDS = Post Discharge Surveillance

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Re-operation as a SSI-risk in breast surgery

- The risk for SSI after re-operations is reported significantly higher than after primary operations (13,14,17).
- In our retrospective register-based survey, re-operated patients had 2.6-fold (P = 0.003), 2.4-fold (P = 0.017) and 2.7-fold (P = 0.027) risk for SSI compared with primary operated patients among all operated patients, local excision, and mastectomy patients respectively (13).
- In a US cohort study (17), the SSI incidence was 2-fold higher after mastectomy with immediate reconstruction than after mastectomy alone. Only 49% of SSIs were detected within 30-days postoperatively.
- In a study of Throckmorton et al. in 2009 (19) there was no statistically significant association between prior operation within 90 days and SSI rate (P = 1.0).

Procedure specific complications in breast surgery

- Axillary lymph node dissection (ALND) is a classical procedure often completed as a reoperation requiring an additional incision with under arm location (20,21).

- In a Cochrane Review, ALND is reported resulting more likely lymphoedema compared with Sentinel Lymph Node Biopsy (SLNP) with no significant differences in overall survival of the operated patients. Full axillary clearance without clinically and radiologically involved axilla is no longer considered acceptable practice (20).

- A recent study challenged the high costs and long operative time of standard procedures by suggesting possibility to avoid intraoperative Frozen Section (iFS) in most cases of early-stage clinically and radiographically node-negative breast cancer patients without a significant impact on the overall quality of treatment and standard of care (21).

Procedure specific complications in breast surgery

- Breast reconstruction has a positive impact on the body image and quality of life for women after experiencing the physically and psychologically demanding processes (22) but the positive experience may be threatened by postoperative complications.
- Impaired wound healing (18.3%), seroma (6.1%), haematoma (4.6%), capsular contraction (4.6%) and infection (3.8%) reported existing after breast reconstruction operations (23).
- Postoperative complications, 3.1-fold (P = 0.017) SSI rates or impaired healing; 3.8-fold (P = 0.020) SSI or impaired healing requiring surgery reported due to the implant used as a temporary spacer for delayed immediate autologous reconstruction compared with no spacer. The explantation of the implant occurred after 16.3% of procedures. Other risks for complications were the surgeon, higher drain volume during the last 24 h, higher implant volumes, higher resection weight, and incision type. (24)
- In a study of Alves et al. published in 2022, no significant differences reported in haematomas, infections, flap necrosis, and in partial or total flap loss between immediate and delayed deep inferior epigastric perforator flap operations but higher prevalence of wound healing issues (healing delayed, dehiscence, and superficial skin necrosis) in delayed breast reconstructions, probably linked to complex care processes including radiation or chemotherapy interfering the healing process. (25)

Surgical drains as SSI risks in breast surgery

- After breast operations, patients usually have one or more surgical drains removing bleeding and leak from the surgical site. The criteria for drain removal vary. Some surgeons remove the drain according to the postoperative day (E.G. day 3), some by drain volume (E.G. 30 ml) per day or per patient defined criteria.
- Drain volume is reported varying according to the surgical interventions and techniques used. After the subcutaneous placement of breast implants or expanders after a mastectomy without biological matrices or synthetic meshes the drains remained for a mean of 5.9 days (SD 3.1), producing a mean cumulative volume of 458.3 ml (SD 521.9) with the mean volume of 16.7 ml (SD 11.5) within the last 24 hours. The association between the high drain volume during the last 24 h and explantation of the breast implant was reported statistically significant ($P = 0.045$). (23)
- In our study, the existence of a surgical drain predicted 3.3-fold ($P = 0.003$) risk for SSI among all breast operated patients and 3.2- fold ($P = 0.008$) risk was among local excision patients. Among mastectomy-patients the risk was not statistically significant. (13)

Variations in measuring patient related SSI-risks in breast surgery

- In a recent US study, the variation in SSI rates reported in association with chronic obstructive pulmonary disease (COPD), diabetes, smoking, ASA class-severe, BMI > 35 kg / m^2, and length of hospital stay (LOS) more than one day (9).

- BMI > 25 kg / m^2 was reported as a risk for SSI in lobectomies and mastectomies (13).

- BMI > 30 kg / m^2 was not reported as a risk following implant-based breast reconstructions (19).

- In a large scale studies, the BMI > 35 kg / m^2 in addition to smoking and DM, were reported as SSI-risks in lumpectomies and mastectomies (9,14).

Examples of SSI-risks in breast surgery with debatable evidence

- The breast cancer patients' preoperative hospital visits include invasive interventions like core needle biopsy, and placement of a wire or other localizing device prior to the surgical procedure challenging the requirement for intact skin in the operational site but not having clear association with SSI (9).
- In our past study in lobectomy and mastectomy patients (N=982) nurses reported the skin of the patient in the surgical site intact for 80% of the operations, and signs of preoperative infection in six per cent. Nurses documented preoperative invasive procedures in 55% of the operations. A sentinel puncture was completed in 10% of the operations, wire marking in 35% and other punctures (e.g. blue ink application) in three per cent of the operations. The rest of the patients had anaesthesia-related punctures.(13)
- The evidence related to the risk of preoperative invasive procedures is not free from bias due to the challenges in retrospective data collection and documentation (13,9).

Conclusions

- Securing aseptic safety in breast operations is important due to the variation in the numerous general, patient and the procedure related SSI-risks.
- It is crucial to further develop procedure specific process indicators enabling the implementation and measurement of patient, occupational and environmental aseptic safety in breast surgery.
- The implementation and follow-up of procedure specific infection prevention and control measures require relevant structure indicators and evaluation models validated in breast surgery.

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Thank you all for this opportunity to share my interests with all the eBreast 11 partners!

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