THE IMPACT OF OBESITY ON SURGICAL SITE INFECTIONS IN LOW RISK PROCEDURES: A SYSTEMATIC REVIEW

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Abstract

Background: While obesity has been identified as a risk factor for post-operative surgical site infections in general, it is unclear if obesity is a risk factor for surgical site infections for low risk surgeries.

Methods: A systematic review was conducted by searching PubMed, EMBASE, CINAHL and hand searching the references of included studies. Articles were included if the type of surgical procedure was low risk regardless of type of setting where the research was undertaken. All studies that used any obesity measurement were included if surgical site infections were the outcome of interest.

Results: Three hundred and twenty-nine articles from three databases were identified. A full-text review of 58 articles that met inclusion criteria yielded 19 studies that were included in the analyses. Six studies had good study quality, 10 studies had fair study quality and three studies had poor study quality. Variations were noted among these studies in relation to definition of surgical site infection and cutoff levels used to define obesity. Due to heterogeneity of the definitions for surgical site infections, cutoff points for obesity and comparators, and variability of study quality, results from the studies could not answer the research question.

Conclusion: The relationship between surgical site infections and obesity in the context of low risk surgeries is not yet determined. Future research should focus on patient safety reviews for low risk procedures, determine best methods to accurately measure obesity, and review obesity as a risk factor for patients undergoing low risk surgeries in all settings.

Lay Summary

The purpose of this study was to review published research articles that evaluated whether someone who is above normal weight is more likely to get an infection at the site of surgery after any low risk surgery than someone who is normal weight. The definition for a low risk surgery is surgery that does not carry a risk for heavy bleeding, and does not require admission to a hospital to recover. Of 329 research articles found, 19 were included for review. The outcomes of the research articles could not be compared for several reasons: i) the definitions for infections were different between the studies, ii) a variety of low risk surgeries were included that could not be compared to each other, and iii) the studies used different cut-off criteria for above normal weight. Therefore, because of the variation found in the research results, this review could not infer a relationship between patients being above normal weight and the development of infections at the site of a low risk surgery.

Preface

This master's thesis is an original intellectual product of the author, Sandra Daniels. Committee members provided feedback as well as assistance with design and analysis. There was no requirement to obtain approval from the ethics committee for this thesis due to the nature of the study design (Systematic Review).

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List of Abbreviations

Abbreviation	Explanation
AAAHC	Accreditation Association for Ambulatory Health Care
ASA	American Society of Anaesthesiologists
ASA score	American Society of Anaesthesiologists Physical Status Classification system
BMI	Body mass index
HCUP	Healthcare Cost and Utilization Project
HICPAC	Healthcare Infection Control Practices Advisory Committee, US-CDC
NIH	National Institute of Health
NNIS	National Nosocomial Infections Surveillance
OSA	Obstructive Sleep Apnea
PICO	Patient population or problem (P), intervention (I), comparison or control (C) and outcome(s) of interest (O)
PICNet	Provincial Infection Control Network
SSI	Surgical site infection
U.S.-CDC	U.S. Centers for Disease Control and Prevention
U.S.-SASD	U.S. State Ambulatory Surgery and Services Databases
U.S.-SID	U.S. State Inpatient Databases
WHO	World Health Organisation

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Dedication

I dedicate this paper to my loving husband Chris and children Rebecca and Natalie who allowed my absenteeism, my fits of anxiety, and my inability to keep the house clean with graciousness and acceptance.

Special thanks are owed to my parents, David and Nancy Carter who have supported me mentally, morally and financially throughout my decades of education.

In memory of my brother Rick who lived life passionately and died too young.

Chapter 1: Introduction

1.1 Overview

Obesity is the second leading cause of preventable death and has reached epidemic proportions (Buchwald & Oien, 2013; Haslam, 2011). Obesity is a well-documented risk factor for multiple comorbidities (Haslam & James, 2005) including surgical site infections (SSIs) (Jiang, Teng, Fan, Khan, & Xia, 2014; Ma, Guo, Qi, Xiang, & Zhang, 2016; Yuan & Chen, 2013). Several meta-analyses have been undertaken to examine the relationship between SSIs and obesity and have found that obesity is a risk factor for increased surgical site infections (Abdallah, Jadaan, & McCabe, 2013; Liu, Dong, Wu, Chen, & Wang, 2016; Ma et al., 2016; Yuan & Chen, 2013). Over the past 30 years, surgical care has shifted from the inpatient to outpatient setting, in large part due to advances in anesthesia and the development of laparoscopic surgery that make surgeries that were previously classified as high risk to now be considered low risk surgeries (Chin et al., 2016; Jevtovic-Todorovic, 2006; Mathis et al., 2013; Sloss & Medicare Payment Advisory, 2006). As such, low risk surgeries are increasing in number, but it is unclear if the relationship between obesity and SSIs holds true for low risk surgeries.

1.2 Obesity and Body Mass Index

The World Health Organization (1998) defines obesity as "a condition with excess body fat to the extent that health and well-being are adversely affected" (p. 7). Once more prevalent in industrialized and urban areas, many low- and middle-income countries are now facing an obesity crisis (World Health Organization: Division of Noncommunicable Diseases and

Programme of Nutrition Family and Reproductive Health, 1998). The worldwide prevalence of obesity more than doubled between 1980 and 2014 (World Health Organisation, 2015). By 2014, the WHO estimated that more than 1.9 billion adults (38% of men and 40% of women) were overweight and more than 600 million adults (11% of men and 15% of women) were obese.

Obesity is known to reduce quality of life (Livingston & Ko, 2002) and life expectancy itself (Berrington de Gonzalez et al., 2010; Flegal, Graubard, Williamson, & Gail, 2005; Manson et al., 1995). Being obese is associated with increased risk of some serious medical conditions. These include diabetes, stroke, heart disease, gall bladder disease, high cholesterol, gout, osteoarthritis, certain cancers and breathing disorders such as asthma and sleep apnea (Dhurandhar, Bailey, & Thomas, 2015; Grundy & Barnett, 1990; Haslam & James, 2005). Increased weight puts a greater demand on the musculoskeletal system leading to an amplified incidence of degenerative disease in the leg joints and lumbar spine (Coggon, Reading, Croft, & McLaren, 2001; Miller, Schmatz, & Schultz, 1988).

1.3 Patient Safety and Surgical Site Infections

Over the past 20 years, patient safety initiatives have increasingly been recommended and implemented (Brachman et al., 1980; Classen et al., 2011; Haley, Culver, Morgan, et al., 1985; Horan et al., 1993; Leape, Berwick, & Bates, 2002; Mangram, Horan, Pearson, Silver, & Jarvis, 1999; Manian & Meyer, 1990). Patient safety initiatives are practices "that reduce the risk of adverse events related to exposure to medical care…" (p. v) (Shojania, Duncan, McDonald, Wachter, & Markowitz, 2001). The term adverse event is often used interchangeably with other terms such as sentinel event, adverse outcome and critical incident. An adverse event

"results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition" (p.59) (Canadian Patient Safety Institute, n.d.-a). A fundamental purpose of many healthcare initiatives is to provide consistent data about trends of adverse events and evidenced-based measures for improvement (U.S. Agency for Healthcare Research and Quality, 2008). Several analyses of the healthcare system have identified the most common adverse events and found that approximately 50 percent of adverse events were deemed preventable, including approximately 70 percent of all infections (de Vries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2008; Wilson et al., 1995).

Infections acquired in healthcare settings are the third leading cause of adverse events (Classen et al., 2011). A surgical site infection (SSI) is defined as "an infection that occurs after surgery in the part of the body where the surgery took place" (para. 1) (U.S. Centers for Disease Control and Surgical Infection Society, 1992). There are two main types of SSIs: Superficial and Deep. *Superficial infections* involve the skin and subcutaneous tissues, whereas *deep infections* can involve any other tissues including muscles, organs, or implanted material (Astagneau, Rioux, Golliot, & Brücker, 2001; U.S. Centers for Disease Control and Prevention, 2010). SSIs remain a major risk factor for increased morbidity and mortality rates and poor outcomes among surgical patients (Astagneau et al., 2001; Canadian Patient Safety Institute, n.d.-b).

1.4 Obesity, Surgical Site Infections and Low Risk Surgical Procedures

The patient who is obese presents a challenge to both surgical technique and variation of equipment required. Several meta-analyses have demonstrated that patients who are obese have more SSIs (Dhurandhar et al., 2015; Jiang et al., 2014; Tan et al., 2010; Xing et al., 2013).

Higher SSI rates for patients who are obese may be due to longer operation times, deeper operating fields, deeper spaces where infection can set in, and reduced blood flow in fat tissue; all of these can result in delayed healing and increase the risk of an SSI (Dhurandhar et al., 2015; Jiang et al., 2014). Technological advances, faster acting and more effective anesthetics, and less invasive techniques, such as arthroscopy, have allowed a growing range of procedures to be classified as low risk (U.S. Centers for Medicare and Medicaid, 2011). However, the relationship between obesity and SSIs in a subset of patients that are undergoing low risk procedures has not been examined.

1.5 Significance

Although obesity is increasingly common in patient populations and has been documented as a risk factor for SSIs, to date, no systematic review has provided a synthesis on existing literature on the impact of obesity on SSI rates for low risk procedures.

1.6 Purpose

The purpose of this thesis is to review, critically appraise and synthesize existing evidence from eligible studies to identify whether obesity is a significant risk factor for surgical site infections in low risk surgeries.

1.7 Research Question

One research question will be examined in this thesis: Is obesity a risk factor for surgical site infections in low risk surgeries?

1.8 Conclusion

This thesis explores the evidence about the impact of obesity on SSI rates in low risk surgeries. The results may help to identify gaps requiring attention to strengthen the quality of future studies. The outcome may also have implications for providers, policy makers, patient selection criteria and patient decision making.

Chapter 2: Literature Review

2.1 Introduction

In this chapter an overview of relevant literature is presented. The chapter describes low risk surgical procedures, patient safety, surgical site infections (SSIs), SSI classification criteria, reduction strategies for SSIs through modifiable risk factors, and obesity as a modifiable risk factor. The chapter is closed with a discussion of tracking of SSIs through surveillance methods and national databases.

2.2 Low Risk Surgical Procedures

Surgical procedures are interventions involving an incision with instruments by a healthcare specialist that involve using anaesthesia and/or providing respiratory assistance (Organisation for Economic Cooperation and Development, 2015). Procedures that previously required major incisions, long-acting anesthetics and extended recovery can now be performed through less invasive techniques such as laparoscopy, utilization of short-acting and reversible anaesthetics allowing for shorter recovery time (U.S. Ambulatory Surgery Center Association, 2015). These advancements, which shorten length of stay in hospital and speed recovery following surgery, have led to a trend towards more procedures being carried out in outpatient settings (Mathis et al., 2013; U.S. Ambulatory Surgery Center Association, 2015). There are typically two types of outpatient surgeries: short stay cases and extended stay cases. *Short stay cases* are those that do not require an overnight stay for post-operative (post-op) monitoring, whereas *extended stay cases* are those in which post-op recovery requires an overnight stay but lasts less than 24 hours and does not require admission to the hospital. As medical innovations

continue to advance, more people opt for surgery and hospitals are unable to cope with numbers of admitted patients, more low risk procedures will be carried out in outpatient surgical settings (U.S. Ambulatory Surgery Center Association, 2015).

According to the Accreditation Association for Ambulatory Health Care (AAAHC), an independent expert group of accreditors that maintains a current list of U.S. state laws and regulations on independent Ambulatory Health Care, inclusion and exclusion criteria for patients undergoing surgery in an outpatient setting must be met (Accreditation Association for Ambulatory Health Care Inc., 2015). In British Columbia, the Ministry of Health published a Future Direction white paper that identifies there is an increased demand for surgical procedures (B.C. Ministry of Health & The Provincial Surgical Executive Committee, 2015). The increased demand is caused by a growing and aging population, an increasing prevalence of obesity, improvements in surgical procedures and technology, and patients driving the need for elective surgery to improve one's quality of life (B.C. Ministry of Health & The Provincial Surgical Executive Committee, 2015).

Patient-centred care supports people to make informed decisions about their preferences or choice in choosing surgeries. Elective low risk procedures are in increased demand as younger, healthier and fitter people opt for less invasive surgeries with the goal to improve quality of life (Bebbington & Furniss, 2015; Conrad, 2007; Siciliani & Hurst, 2005). There is debate about who should have elective surgeries or surgeries deemed not medically necessary (Accreditation Association for Ambulatory Health Care Inc., 2015; Open Anaesthesia, 2016; The American Congress of Obstetricians and Gynecologists, 2013). There is need to develop evidence to support patient decisions in this emerging field of healthcare.

2.2.1 American Society of Anaesthesiologists Physical Status Classification System

In Canada and the U.S., the American Society of Anaesthesiologists Physical Status Classification system (ASA score) is a grading system widely used to subjectively evaluate the preoperative health of surgical patients (American Society for Anesthesiologists, 2014). The ASA score is separated into six classes (I to VI) that includes normal healthy, mild systemic disease, severe systemic disease, severe systemic disease that is a constant threat to life, moribund and not expected to live without the operation and brain-dead for organ removal (American Society for Anesthesiologists, 2014). Low risk patients fall into ASA categories I-II and potentially category IIIs if they do not require complex or long-duration monitoring postoperatively. Patients rated as classes IV – V are deemed high risk for poor outcomes after surgery. The limitation of this classification system is that it does not specifically consider a patient's physiological variables such as weight, surgical variables such as type and depth of the surgery, or the anaesthesiologist's or surgeon's skill level or the care provided to the patient. Therefore, while suitable for patient selection, it does not capture all patient risk factors. Due to its limitations, the ASA grading system should not be used to predict operative risk (American Society for Anesthesiologists, 2014), but instead to act as a general guide for including or excluding patients from different types of surgeries or settings.

There are currently five exclusion criteria that would prohibit a person from receiving surgery at an outpatient surgical facility: 1) The procedure is considered major surgery; 2) The procedure has the risk of major blood loss; 3) The procedure is an American Society of Anaesthesiologists Physical Status Classification score of class III or IV requiring complex or long-duration monitoring postoperatively; 4) Any patient with an upper respiratory tract infection, and; 5) Patients who are morbidly obese who have obstructive sleep apnea (OSA)

(OSA alone is not a contraindication) (Open Anaesthesia, 2016). Using these exclusion criteria as a guide, this thesis defines low risk surgical procedures as those that do not meet any of the five exclusions (see Table 2.1) and include surgical procedures that are currently carried out in outpatient surgical settings (Table 2.2). Examples of procedures that are considered low risk are surgeries performed on the eyes, ears, nose, mouth, pharynx; muscle, tendon, and joint repairs (e.g., rotator cuff, tendon sheath, cartilage excision, implant removals) and diagnostics (e.g., arthroscopies with surgical interventions); straightforward digestive system surgery (e.g., hernia repairs, hemorrhoids); uncomplicated surgeries on women (e.g., breast surgery, uterine procedures, abortions), and; some minor skin surgeries (e.g., excisions such as Moh's procedures, circumcisions, and varicose vein treatments) (Open Anaesthesia, 2016; Statistics Canada, 2000). The U.S. Healthcare Cost and Utilization Project (HCUP), 2012 U.S. State Ambulatory Surgery and Services Databases (U.S.-SASD) and 2012 U.S. State Inpatient Databases (U.S.-SID) reflect similar low risk procedures that can be undertaken in American outpatient surgical centres (Barrett, Lopez-Gonzalez, Coffey, & Levit, 2014). Increasingly, some procedures such as knee replacements and lumbar spinal surgeries are also deemed low risk procedures (Chin et al., 2016; Dyrda, 2015). Table 2.1 shows a summary of inclusion criteria for low risk surgical procedures. Table 2.2 summarizes organ systems and low risk procedures associated with each (Barrett et al., 2014; Dyrda, 2015; Open Anaesthesia, 2016; P. Owens, Barrett, Raetzman, Maggard-Gibbons, & Steiner, 2014; Statistics Canada, 2000).

Table 2.1 Inclusion and exclusion criteria for low risk surgeries

Scope of Surgery
No risk of major blood loss
Elective surgeries that are not considered major surgeries (e.g. breast surgery)
Minor surgery such as varicose vein treatments
Patient Characteristics
ASA categories I-II included, III considered
Patients with upper respiratory tract infection (URTI) excluded
Patients who are morbidly obese with obstructive sleep apnea (OSA) excluded

Table 2.2 Organ systems and examples of low risk procedures

Organ System	**Low Risk Procedure Examples**
Ears, nose, throat	Eyes, ears, nose/mouth/pharynx
Muscle, tendon, bones and joints	Repairs such as rotator cuff, anterior cruciate ligament, tendon sheath, cartilage excision, total knee arthroplasties, implant removals, elective spine, anterior access at lumbar level
Skin surgeries	Excisions such as Moh's procedures, circumcisions, and varicose vein treatments, and plastics such as elective procedures for weight loss and body lifts after weight loss
Diagnostics (with surgical interventions)	Arthroscopies
Digestive system	Hernia and hemorrhoids repairs
Surgeries on women	Breast surgery, uterine procedures, abortions
Respiratory	None
Cardiovascular	None
Urinary	None

2.3 Surgical Site Infections

SSIs are one of the most common adverse events in healthcare (Zoutman, McDonald, & Vethanayagan, 1998). Worldwide, 7 to 10 out of 100 people will acquire at least one healthcare associated infection including SSIs (World Health Organisation, 2009). In a U.S. study from 2009, De Lissovov and colleagues estimated that for the 27 million surgical procedures conducted each year two SSIs occur for every 100 procedures (de Lissovoy et al., 2009; Mangram et al., 1999). SSI incidence varies from 0.5 to 37% depending on the type of surgical procedure, underlying patient status, and location (Cruse & Foord, 1980; Horan et al., 1993). Researchers have estimated that in Western countries the frequency of SSIs is 1 in 5 for all types

of surgery and 1 in 10 for all general surgeries (Coello, Gastmeier, & Boer, 2001; Horan et al., 1993; Jodrá et al., 2006; U.S. National Nosocomial Infections Surveillance System, 2004). WHO statistics show that globally, SSIs account for about 15% of all health-care-associated infections and about 37% of all infections acquired by surgical patients (Broex, Van Asselt, Bruggeman, & Van Tiel, 2009; C. Owens & Stoessel, 2008; Smyth & Emmerson, 2000; Zhan & Miller, 2003).

In 1988, the United States Centers for Disease Control and Prevention (U.S.-CDC) published their consensus definitions for surgical site infections (Garner, Jarvis, Emori, Horan, & Hughes, 1988). An SSI was defined as an infection that occurs at or near the surgical incision and sub-classified into two types, either localized to the incision site (superficial infection) or extending into deeper adjacent structures (deep or organ space infections) (Horan et al., 1993). In 1992, the U.S.-CDC collaborated with HICPAC and the NNIS to further expand SSI definitions (Horan et al., 1993; Mangram et al., 1999) in which they defined the diagnostics required for an infection to meet SSI criteria, significantly changing SSI inclusion criteria for data collection. Despite being more than twenty years old, these updated definitions are considered the gold standard (Mangram et al., 1999; U.S. Centers for Disease Control and Prevention, 2010, 2016). In 2016, the US-CDC updated the criteria for length of time from surgery an SSI should be classified however the clinical identification for SSIs remain unchanged (U.S. Centers for Disease Control and Prevention, 2016). Table 2.4 shows current definitions of SSIs. Appendix C shows the progression of definitions across the years.

Table 2.3 Definition of surgical site infections 2016 (from U.S.-CDC)

Term	2016 Definition
Operative procedure definition	Operative procedure is a procedure that: takes place during an operation where at least one incision (including laparoscopic approach) is made through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure AND Takes place in an operating room (OR), defined as a patient care area that met the Facilities Guidelines Institute's (FGI) or American Institute of Architects' (AIA) criteria for an operating room when it was constructed or renovated Exclusion ASA score of VI
Superficial Incisional	Infection occurs within 30 days after procedure and involves only skin or subcutaneous tissue of the incision AND at least one of the following: • Purulent drainage from the incision • Organisms identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment • Superficial incision that is deliberately opened by a surgeon, attending physician** or other designee and culture or non-culture based testing is not performed PLUS one of: -Pain or tenderness -Localized swelling -Redness or heat • Diagnosis of superficial SSI by the surgeon or attending physician
Deep Incisional	Infection occurs within 30 or 90 days[1] after the NHSN operative procedure according to the list presented by the CDC involves deep soft tissues (fascial and muscle layers) AND at least one of the following: • Purulent drainage from the deep incision (fascial and muscle layers) • Spontaneously dehisces or is deliberately opened by a surgeon, attending physician** or other designee and organism is identified by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment OR culture or non-culture based microbiologic testing method is not performed AND patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or tenderness • An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test
Organ space	Infection occurs within 30 or 90 days after the NHSN operative procedure according to the list presented by the CDC AND infection involves any part of the body deeper than the fascial/muscle layers, that is opened or manipulated during the operative procedure AND patient has at least one of the following: • purulent drainage from a drain that is placed into the organ/space (e.g., closed suction drainage system, open drain, T-tube drain, CT guided drainage) • organisms are identified from an aseptically-obtained fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment. • an abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test AND meets at least one criterion for a specific organ/space infection site listed in CDC Table[2]

[1]The only low risk procedures that meet the 90-day surveillance requirement for SSI are breast surgery, lumbar spinal fusion, and knee prostheses (TKA). All other procedures require 30 day surveillance

[2]Organ space SSIs that are associated with low risk procedures would be bone (osteomyelitis), breast (abscess or mastitis), lumbar spine (disc space, spinal abscess), eye (any infection other than conjunctivitis), bariatric surgery (intraabdominal), TKA (joint infection or periprosthetic infection), oral cavity (any infection of the mouth, tongue or gums), skin infection, soft tissue infection.

Note. Table reprinted with permission from Surgical Site Infection (SSI) Event by U.S.-CDC, retrieved from http://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf. Copyright 2016 by U.S.-CDC

SSIs can vary in location and intensity depending on risk factors. Two thirds of SSIs are incisional (superficial infections) and one third are confined to the organ space (deep infections) (Alexander, Solomkin, & Edwards, 2011; Smyth & Emmerson, 2000). SSI infection risks can be impacted by procedural factors and characteristics of the patient. Procedural factors include 1) the invasiveness of the procedure (more invasive procedures lead to a higher risk) (Cizik, Lee, Martin, & Bransford, 2012), 2) the length of the procedure (the longer the procedure the higher the risk) (van Walraven & Reilly, 2013), 3) whether a prosthesis or instrumentation is inserted (instrumentation increases the risk for an SSI), and 4) the type of procedure (patients undergoing knee arthroscopy are at lower risk for an SSI than patients undergoing abdominal and thoracic surgeries) (C. Owens & Stoessel, 2008). Characteristics of the patient include 1) number of comorbidities (sicker patients have higher risk of an SSI) and 2) lifestyle behaviours such as smoking (smokers are at a higher risk of developing an SSI) (Fisichella, Fenga, & Rosa, 2014; Mangram et al., 1999).

It is important to understand that an SSI is a risk factor that can increase morbidity and mortality rates as well as extend length of stay and costs related to increase healthcare needs. One longitudinal US study noted that patients who developed an SSI had double the mortality rate regardless of surgery type, had more than twice the risk of requiring care in an intensive care unit, and were more than five times more likely to require readmission (Kirkland, Briggs, Trivette, Wilkinson, & Sexton, 1999). In England, one study indicated the mortality rate for patients with deep SSIs compared with those without SSI was highest for vascular surgery, hip replacements and gastrointestinal surgery (Coello et al., 2005). In another U.S. study, patients who underwent coronary artery bypass grafting and developed a deep SSI were 36 times more likely to die than patients who did not develop an SSI (Hollenbeak et al., 2000). Variation in the

patient population itself also changes mortality rates; elderly populations (>65 years old) are almost three times more likely to die from an SSI compared to younger patients (McGarry, Engemann, Schmader, Sexton, & Kaye, 2004). An SSI can increase postoperative hospitalizations of up to an additional twenty days and therefore SSIs have a considerable impact on hospital costs (Brachman et al., 1980; Fabry et al., 1982; Kirkland et al., 1999; C. Owens & Stoessel, 2008; Probhakar et al., 1983) SSI can also be very costly. A Canadian study from 1998 found that each SSI adds an additional cost of CAN$3,700 to the healthcare system (Zoutman et al., 1998). In a 2002 U.S. study, treating SSIs can cost between U.S.$400 to more than U.S.$30,000 (Fry, 2002). A 2001 study of NHS hospitals estimated that an average of 321,000 patients annually acquire one or more infections which cost an estimated £930.62 million (average £345/SSI) (Plowman et al., 2001). German researchers showed that SSIs increased cost by between U.S.$3,859 and U.S.$40,559 (Fry, 2002). Researchers estimate SSIs more than double the cost of health care and increase length of stay more than three times longer (Broex et al., 2009).

2.4 Efforts to Reduce Surgical Site Infections

SSIs and their preventable risk factors have become a primary focus for patient safety initiatives to reduce the rates of surgical adverse events (Berenguer, Ochsner, Lord, & Senkowski, 2010). Although measurement of adherence to risk reduction strategies is difficult, identification of risk factors allows for corrective interventions prior to and during surgery to attempt to improve patient outcomes (Larochelle, Hyman, Gruppi, & Osler, 2011; Serra-Aracil et al., 2011; Wick, Gibbs, Indorf, Varma, & Garcia-Aguilar, 2008).

In 2008, the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) published a practice guide to preventing surgical site

infections based on the U.S.-CDC guidelines which has since been updated (Anderson et al., 2014; Yokoe et al., 2014). Table 2.4 summarizes preventable risks and risk reduction strategies identified in the SHEA and IDSA paper.

Table 2.4 Modifiable risk factors for surgical site infections

Patient Risk Factors	
Risk	Risk Reduction Strategy
Diabetes	Glucose control
Obesity	Lose weight prior to surgery; increase of prophylactic antimicrobials
Nicotine use	Smoking cessation a minimum of 30 days before the procedure
Immunosuppression	Avoid immunosuppressive therapy/steroids during perioperative period if possible
Pre-operative infections	Identify and treat remote infections (e.g. urinary tract infections), preoperative antiseptic showers
Procedural Risk Factors	
Risk	Risk Reduction Strategy
Hair removal	Avoid hair removal or clip instead of shave
Surgical scrub for surgical team members' hands and forearms	Always perform a surgical scrub
Incision preparation	Wash and disinfect skin around incision using an appropriate skin antiseptic
Antimicrobial prophylaxis (pre-intra- and post-operative)	Follow recommended timing, choice and duration as appropriate
Asepsis	Pre-op skin antisepsis, surgical attire and drapes, sterility of instruments, incision care and dressings
Length of procedure	Minimize length of procedure
Operating room environment	HVAC (temperature, humidity, air flow), limit traffic, environmental surface disinfection between cases

2.5 Tracking Surgical Site Infections

Surveillance is defined as the "systematic, ongoing collection, collation and analysis of data with timely dissemination of information to those who need to know so that action can be taken" (Park & Allaby, 2017). In 1980, Haley completed the seminal Study on the Efficacy of Nosocomial Infection Control (SENIC Project). Conclusions were reached that a comprehensive, organized surveillance program staffed appropriately was associated with reduced rates of healthcare associated infections (Haley, Culver, White, et al., 1985). Routine

surveillance for SSIs is recommended by both the U.S.-CDC (Mangram et al., 1999) and the Surgical Infection Society (U.S. Centers for Disease Control and Surgical Infection Society, 1992) as a mechanism for reducing the rate of SSIs. SSI surveillance has been associated with decreased infection rates cited as somewhere between 15-35%, (Brandt et al., 2006; Haley, 1986; Haley, Culver, White, et al., 1985; Provincial Infection Control Network (PICNet), 2006). The cost of surveillance has been estimated to be about one-fifth to one-third the cost of treating preventable infections (Condon, Haley, Lee, & Meakins, 1988; Olson & Lee, 1990; Provincial Infection Control Network (PICNet), 2006). Even if the effect of surveillance was only found in the lower range, it would be a cost-effective initiative. Surveillance is only one step in rate reduction. Part of any patient safety initiative is knowing the extent of a problem and this can be accomplished through benchmarking and comparison to facility averages to gauge the performance of a facility (Makary et al., 2006).

The U.S. National Healthcare Safety Network (U.S.-NHSN) incorporates the U.S. National Nosocomial Infections Surveillance (U.S.-NNIS) system to gather data on healthcare associated infections including SSIs. Some Canadian healthcare organizations also participate in a national database through the Canadian Nosocomial Infection Surveillance Program (CNISP) surveillance network (Public Health Agency of Canada, 2012). These programs aggregate the data received from a variety of facilities to determine average rates of infection while controlling for confounders. The U.S.-NNIS took the information a step further and developed a risk index scoring system that predicts the risk of a patient developing any healthcare associated infections based on indicators such as patient demographics and comorbidities and procedure factors such as procedure type, skill of physician, and use of prostheses. However, obesity has not been included in the risk index scoring system despite being identified as a modifiable risk in other

research (de Oliveira, Ciosak, Ferraz, & Grinbaum, 2006; Pastor et al., 2010). Currently, incomplete data sets occur because the majority of facilities that feed the national databases are hospitals and not outpatient surgical settings (U.S. National Research Council (US-NRC) of the National Academies, 2013). Additionally, aggregated data are only useful if working definitions for data collected are comparable (U.S. National Research Council (US-NRC) of the National Academies, 2013).

2.6 Obesity

Obesity has reached epidemic proportions, although there are considerable geographic variations (Berghofer et al., 2008). In the U.S. and Canada, 34 percent of the adult population meets the WHO's definition of obese (a body mass index ≥ 30 kg/m^2), up from just 15 percent in the 1960s (Health Canada, 2003, 2006; Statistics Canada, 2000; U.S. National Institute of Diabetes and Digestive and Kidney Diseases, 2012). Canadian, United Kingdom (UK) and U.S. data all suggest an obesity crisis (Organisation for Economic Cooperation and Development, 2015; World Health Organisation, 2016). At least eight million Americans are morbidly obese (WHO Obese - Class III). In the UK, the rate of adulthood obesity rose from 14.9% to 25.6% between 1993 and 2014 (European Commission, 2015).

Being obese is associated with an increased risk of some medical conditions. Concurrent diseases, also known as comorbidities, that are associated with obesity are more prevalent than found in the general population (Valderas, Starfield, Sibbald, Salisbury, & Roland, 2009). These comorbidities include hypertension, hypercholesterolaemia, hypertriglyceridaemia and Type-2 diabetes (Folsom et al., 2000; Goodpaster et al., 2003; Lakka, Lakka, Tuomilehto, & Salonen, 2002; Liu et al., 2016; Ohlson et al., 1985; Prineas, Folsom, & Kaye, 1993; Rimm et al., 1995;

Seidell, Deurenberg, & Hautvast, 1987; Snijder et al., 2004; Vague, 1999). For Medicaid patients in the U.S., more than 300,000 deaths per year are attributed to comorbidities related to or caused by obesity. Each of these comorbidities also carries a risk for poor post-surgical outcomes including infections (Deyo, Cherkin, & Ciol, 1992; Klasen et al., 2004).

Obesity poses a significant burden; conservative estimates have determined that the U.S. spends about $100 million (USD) per year on obesity and its complications (Anaya & Dellinger, 2006). However, in one estimate using the instrumental variables model, the estimate of U.S. spending in 2005 on adult obesity and related comorbidities was more than $190 billion (USD) (Cawley & Meyerhoefer, 2012). The increasing number of morbidly obese people is generating a new high-risk group of surgical patients (Hurt, Kulisek, Buchanan, & McClave, 2010). In the U.S., six times more bariatric procedures were performed in 2003 than in 1993 (Pope, Birkmeyer, & Finlayson, 2002). Therefore, obesity should be an area of focus for reduction of SSIs as it is determined to be a modifiable risk factor. See Table 2.5 for a list of other modifiable risk factors.

Analysis of obesity can be challenging because there are a variety of ways to define obesity including body weight, body mass index (BMI), body-fat percentage (BF%), abdominal girth, waist-to-hip ratio, and lamina to skin, visceral or subcutaneous fat depths (Lee et al., 2011; Ogden, Yanovski, Carroll, & Flegal, 2007; Tsujinaka et al., 2008). Obesity data are generally poorly captured and are often collected using a variety of definitions (Martin, Chen, Graham, & Quan, 2014), although BMI and BF% are most commonly used.

Body mass index is a mathematical equation (i.e., weight divided by height squared (units in kg/m^2)). The use of BMI as a surrogate measure for body fat percentage (BF%) is justified based on the observation that BMI correlates well with BF% if a person is ≥ 30 kg/m^2 and BMI

is an easy measurement to determine. The WHO reviewed observational studies undertaken in Europe and the U.S. that studied the relationship between morbidity and mortality and BMI in order to determine at what points risk to patient outcomes increased. For that project, the WHO defined obesity as "a condition with excess body fat accumulation to the extent that health and well-being are adversely affected" (World Health Organization: Division of Noncommunicable Diseases and Programme of Nutrition Family and Reproductive Health, 1998). WHO then suggests cutoff points for overweight (BMI≥25 kg/m^2) and obesity (BMI≥30 kg/m^2) based on the standard deviation (SD) criteria from their test subjects (+1 SD = overweight; +2SD = obesity). Table 2.5 shows the classification system adopted by Health Canada and WHO which identifies accepted cutoff values for BMI and obesity (Health Canada, 2006; World Health Organisation, 2009).

Table 2.5 BMI classification of health risk by Health Canada and WHO

Category	BMI (kg.m^2)	Risk of developing health problems
Underweight	Less than 18.5	Increased
Normal	18.5-24.9	Least
Overweight	25.0-29.9	Increased
Obese – Class I	30.0-34.9	High
Obese – Class II	35.0-39.9	Very high
Obese – Class III	40.0+	Extremely high

Note. From *Obesity*Health Canada, retrieved from http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/obes-eng.php Copyright 2006, Ottawa, Canada and adapted from *The International Classification of adult underweight, overweight and obesity according to BMI*, by The World Health Organisation, retrieved from http://apps.who.int/bmi/index.jsp?introPage=intro_3.html Copyright 2009 by WHO Library Cataloguing in Publication Data.

However, the BMI measurement does not capture fat distribution (Gallagher et al., 1996; Goodpaster et al., 2003). This gap in recognizing where fat is located is significant as there are metabolic differences between the position of different fat deposits; these variations influence the risk of disease. Research has shown that the distribution of fat is more important than the overall amount. Excess intra-abdominal (visceral) fat is associated with metabolic disturbances and

increased cardiac disease risk (Rubenstein, 2005; Tchernof & Després, 2013). Additionally, the literature suggests that differences in body composition and weight status, differences in lean and fat body mass as seen in varying ages, sex, and ethnic variations and the distribution affects a person's risk and therefore what weight classification a person should be placed in (Jackson et al., 2002; Ko et al., 2001; Visser, van den Heuvel, & Deurenberg, 1994).

Some researchers suggest that BMI is not the best indicator for measuring obesity (Gallagher et al., 1996; Visser et al., 1994). However, more accurate measurements of distribution of body fat, such as underwater weighing, bioelectrical impedance analysis, and dual-energy X-ray absorptiometry (measurement of fat density) are not practical for routine use because of their increased costs and difficulty in obtaining or analyzing the results (Harris et al., 2000; He, Tan, Li, & Kung, 2001; Iwao et al., 2001; Janssen, Katzmarzyk, & Ross, 2002; Ohrvall, Berglund, & Vessby, 2000; Pouliot et al., 1994; Rissanen, Hamalainen, Vanninen, Tenhunen-Eskelinen, & Uusitupa, 1997). Therefore, body mass index (BMI) remains the most frequently used measurement to determine obesity and the selected cutoff values are assumed to represent the degree of risk to a person's health (Snijder, van Dam, Visser, & Seidell, 2006). See Table 2.6 for a summary of body fat measurements.

Table 2.6 Ability of body fat measurements to estimate total body fat and fat distribution

Measurement tools	Capability of measuring total body fat	Capability of measuring fat distribution	Applicability in large population studies
CT	Moderate	Very high	Low
MRI	High	Very high	Low
DXA	Very high	High	Moderate
Densitometry	Very high	Very low	Low
Dilution techniques	High	Very low	Moderate
BIA	Moderate	Very low	High
BMI	Moderate	Very low	Very high
WC, HC, WHR, SAD	Low	High	Very high
Skinfolds	Moderate	Moderate	High

CT = computed tomography; MRI = magnetic resonance imaging; DXA = dual-energy X-ray absorptiometry; BIA = bioelectrical impedance analysis; BMI = body mass index; WC = waist circumference; HC = hip circumference; WHR = waist-to-hip ratio; SAD = sagittal abdominal diameter.

Note Reprinted with permission from: What aspects of body fat are particularly hazardous and how do we measure them? by Snijder, M., van Dam, R., and Seidell, J. Retrieved from http://ije.oxfordjournals.org/content/35/1/83/T1.expansion.html. Copyright 2006 by Oxford University Press.

2.7 Conclusion

Obesity is a global health crisis with the numbers of obese individuals rising significantly. Despite this dramatic rise, there is a scarcity of evidence-based guidelines to reduce the risk of SSIs in obese surgical patients (Gupta, Schweitzer, Steele, Lidor, & Lyn-Sue, 2008). This chapter reviewed the literature on low risk surgical procedures including ASA classifications and patient safety strategies. A summary of the outcomes of surgical site infections including risk factors, classifying, reducing and tracking SSIs found in the literature was presented. Obesity as a risk factor was also discussed as well as the variability and benefits in obesity measurements. This systematic review examines whether obesity is a risk factor for surgical site infections in low risk surgeries.

Chapter 3: Methods

3.1 Introduction

The intent of a systematic review is to perform a rigorous, critical analysis of current primary evidence by identifying, selecting, and appraising the methodological quality of relevant research studies, then synthesizing the findings to answer a specific research question (The Cochrane Collaboration, 2011). This systematic review was carried out to answer whether or not patients who are obese undergoing low risk procedures are at increased risk for SSIs compared to patients who are not obese. The CENTRAL database was initially searched to determine if a systematic review had been undertaken for this topic. No reviews were identified in the CENTRAL database.

3.2 PICO Question

A relevant research question was developed to ensure that all relevant information was found during the systematic review. A known strategy for clearly defining the research question is the "PICO" method, which breaks the question into four parts that include: the patient Population or Problem, the Intervention (indicator or exposure in the case of observation studies), the appropriate Control or Comparator, and the Outcome(s) of Interest (Oxman et al., 1994; Russell, Chung, & Balk, 2009). The PICO question elements for this review include: population of patients undergoing low risk surgeries; the indicator is the presence of obesity in patients; the comparator is patients who are not obese; and the outcome of interest is surgical site infections. Therefore, the PICO question is: For all patients undergoing low risk surgeries, does the presence of obesity compared to non-obesity increase the risk of surgical site infections?

3.3 Search Strategy

The search strategy followed the recommendations of the Cochrane Collaboration (The Cochrane Collaboration, 2011). Customized subject terms were selected for Medline, EMBASE, and CINAHL and analysis of common text words and the use of MeSH terms exploded for inclusiveness. A range of free-text words were used to ensure related terms and synonyms were captured as well as the use of truncation. Boolean operators were used to ensure retrieved papers captured both weight related information and SSIs. The Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, Medline, EMBASE were searched up to and including May 31, 2016. In addition, indexed reference lists of identified articles were hand-searched for relevant articles.

3.4 Search Terms

Terms denoting obesity were searched combined with terms that identify SSIs as an outcome (Table 3.1).

Table 3.1 Search strategies for CINAHL, Medline and EMBASE

Search Number	Search terms	N articles found
CINAHL (Ebsco)		
1	(MH "Surgical Wound Infection") OR "surgical wound infection" OR (MH "Surgical Wound Dehiscence") OR (MH "Wound Infection+")	4,428
2	(MM "Adipose Tissue Distribution") or (MM "Adipose Tissue+") OR "obesity OR (body mass index or bmi) or body fat percent OR BF% or (adipose tissue/ OR exp adipose tissue, white/ or adiposity/) OR waist to hip ratio OR (waist circumference or waist measurement)	83,169

Table 3.2 Search strategies for CINAHL, Medline and EMBASE (con't)

Search Number	Search terms	N articles found
CINAHL (Ebsco) Cont'd		
3	(MH "Laminectomy") OR "laminectomy" OR (MH "Laminoplasty") OR (MH "Herniorrhaphy") OR "hernia repair" OR (MH "Bariatric Surgery+") OR "bariatric surgery" OR (MH "Arthroscopy") OR "arthroscopy" OR (MH "Arthroplasty, Replacement, Knee+") OR (MH "Arthroplasty, Knee, Unicompartmental") OR (MH "Knee Surgery+") OR "knee replacement surgery" OR (MH "Surgery, Plastic+") OR (MH "Ambulatory Surgery") OR "plastic surgery"	11,041
4	Combine searches 1 AND 2 AND 3	45
5	Limiters - Publication Type: Journal Article; Age Groups: Adult: 19-44 years, Middle Aged: 45-64 years, Aged: 65+ years, Aged, 80 and over	42
Medline (Ovid)		
1	surgical wound infection.mp.	24,221
2	exp Obesity/ or obesity.mp. or exp Obesity, Abdominal/ or exp Obesity, Morbid/	185,911
3	knee replacement.mp. or total knee replacement/ or knee prosthesis/ or knee replacement/ or knee arthroplasty/ or laminectomy.mp. or laminectomy/ or hernia repair.mp. or hernioplasty/ or Bariatric Surgery.mp. or exp bariatric surgery/ or exp jejunoileal bypass/ or exp wrist arthroscopy/ or exp knee arthroscopy/ or exp hip arthroscopy/ or Arthroscopy.mp. or exp shoulder arthroscopy/ or exp arthroscopy/ or exp ankle arthroscopy/ or exp elbow arthroscopy/ or plastic surgery.mp. or exp plastic surgery/	96,970
4	Combine searches 1 AND 2 AND 3	142
5	limit to ("adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)")	95
EMBASE (Ovid)		
1	surgical wound infection.mp. or exp surgical infection/	26,586
2	exp obesity/ or exp abdominal obesity/ or exp diabetic obesity/ or morbid obesity/	395,942
3	knee replacement.mp. or total knee replacement/ or knee prosthesis/ or knee replacement/ or knee arthroplasty/ OR laminectomy.mp. or laminectomy/ OR hernia repair.mp. or hernioplasty/ OR exp stomach bypass/ or Bariatric Surgery.mp. or exp bariatric surgery/ or exp jejunoileal bypass/ OR exp wrist arthroscopy/ or exp knee arthroscopy/ or exp hip arthroscopy/ or Arthroscopy.mp. or exp shoulder arthroscopy/ or exp arthroscopy/ or exp ankle arthroscopy/ or exp elbow arthroscopy/ OR plastic surgery.mp. or exp plastic surgery/	255,882
4	Combine searches 1 AND 2 AND 3	450
5	limit to (article and journal and (adult <18 to 64 years> or aged <65+ years>))	192

3.5 Screening and Inclusion/Exclusion Criteria

For the purpose of this thesis, any paper that included a low risk surgical event and an SSI and that also reviewed weight was included. Ninety-five articles were retrieved from Medline, 192 papers were retrieved from EMBASE, and 42 research papers were retrieved from CINAHL for a total of 329 papers. After duplicates were removed, 299 abstracts remained. Two reviewers (SD & LC) reviewed all abstracts that were retrieved. After the titles and abstracts were screened, 46 potentially relevant citations were retrieved for a full review. In order to minimize selection bias, both reviewers examined each paper independently and then discussed every article to ensure consensus to the rationale for inclusion or exclusion. Once a detailed list of articles was agreed upon, a relational/hand search of the reference lists of selected articles was performed by SD to identify any additional papers. The hand search of reference lists found an additional 12 articles that were added to the full-text review for a total of 58 papers. These articles were screened by both reviewers for inclusion and exclusion criteria and consensus was reached for all articles included.

3.5.1 Inclusion Criteria

Articles were included if they: (1) were English language, (2) were human studies, (3) were research studies, (4) explored low risk procedures as described in Chapter 2, (5) included data for patients who are both obese and non-obese, (6) included surgical site infections as an outcome, and (7) examined the relationship between surgical site infections and obesity. Data were extracted (see Data Extraction Tool in Appendix A) and inputted into an excel spreadsheet.

3.5.2 Exclusion Criteria

Studies were excluded if the procedure was non-surgical such as diagnostic imagery or endoscopy without surgery. Additionally, studies that reported on infections at locations other than at the surgical site (e.g., gastroenteritis, pneumonia, bacteremias and sepsis) were excluded. Studies were excluded if they reported on complex surgeries not historically carried out in outpatient surgical centres (e.g., ASA scores greater than III, cardiac surgery, solid organ transplant, dental, emergency procedures, paediatrics). Articles were also excluded if data presented on low risk procedures could not be separated from data presented on high procedures. For example, papers that presented data about both primary hip and knee arthroplasties were included only if the data about knee arthroplasties were presented separately from the hip arthroplasties. Primary hip arthroplasties are not considered low risk as they are often a result of a fracture requiring urgent surgery, they have a high potential for blood replacement, and require more than 24 hours post-operative care, whereas knee arthroplasties often meet the defined low risk criteria. Lastly, letters, commentaries, reviews, conferences and discussion papers were excluded. Thirty-nine of the 58 papers were excluded. Reasons for exclusion included: a) Procedure(s) did not meet criteria for low risk surgery (n=8); b) SSI was not an outcome (n=4); c) Either an SSI or a weight analysis including obesity was not included (n=15); d) Data for low risk and higher risk procedures were not separated (n=12). Nineteen research papers met all inclusion criteria.

3.6 Data Extraction and Study Quality Assessment

Each of the 19 articles that met the inclusion criteria was rated for quality using the appropriate NIH Tools for cohort (U.S. Department of Health & Human Services, 2014c) or

case-control research design (U.S. Department of Health & Human Services, 2014b) (see Appendix B). The steps used to determine the quality of each study were similar whether a cohort or a case-controlled study was reviewed. For cohort studies, the NIH Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies was used. The case-control studies were reviewed similarly using the NIH Quality Assessment Tool of Case-Control Studies. Each of the questions was answered based on the article. For "no" responses, studies were reviewed for flaws that would lead the reader to doubt the results or to believe that accurate assessment is not achievable. These were considered fatal flaws that automatically moved a study into the poor category. Target population and participation rate were reviewed to determine if there was a possibility of selection bias.

Reliability and validity of obesity measurements and definitions for SSIs were reviewed to determine if there was potential for measurement bias. As the majority of obesity definitions used BMI, BMI itself did not influence the quality. However, if a validated measurement was used, the study was considered higher quality. Sample size justification was reviewed to determine if research question was exploratory and hypothesis-generating or intended to ultimately determine risk. If meant to determine an outcome, studies that had a power analysis were considered of higher quality; those that did not have a power analysis were deemed lower quality. Timeframes were assessed to determine if the follow-up period encompassed the US-CDC SSI definitions. Responses to follow-up questions may have reduced the quality measurement if follow-up was passive (i.e., if patients were required to initiate the follow-up based on concerns) versus active (e.g., the department routinely scheduled follow-up appointments or phone calls). The quality rating was reduced if losses to follow-up were more

than 20% of total patients. The number and types of confounders adjusted for were reviewed. The more appropriate confounders that were adjusted for, the higher the rating awarded.

The intent of appraising the quality of each study is to identify the weight the results carry during aggregation of the data (Haidich, 2010). Study quality evaluation was conducted by one reviewer (SD) and verified by a second reviewer (LC). Articles were rated as good, fair or poor based on the NIH rating system for risk of bias and therefore the internal validity of the results (U.S. Department of Health and Human Service U.S. Government, 2014). Any articles that were not agreed upon were discussed until consensus was reached.

3.7 Study Synthesis and Data Analysis

The intent of synthesizing the findings is to provide a description of the study results found within the information gathered. The differences between study results were investigated and summarized. Comparisons included facility types, and countries of origin, BMI ranges, SSI definitions and results of risk analysis of patients who are obese. Meta-synthesis was not possible due to significant heterogeneity in the types of surgeries and measurement of obesity

3.7.1 Surgical Site Infections

U.S.-CDC defines three levels of infections; superficial, deep incisional and organ space, research often combines the final two into a single “deep” designation. Because of the variability in reporting of SSIs, any measurement of a post-operative infection was included.

3.7.2 Measurement of Obesity

Because of the variability in definitions, all indices for body weight and obesity were included for review and comparison.

3.8 Conclusion

This systematic review was carried out to answer whether or not patients who are obese and who are undergoing low risk procedures are at increased risk for SSIs compared to patients who are not obese. A relevant research question using the PICO method was developed to ensure that all relevant information was found during the systematic review. The Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, Medline, EMBASE were searched up to and including May 31, 2016. For the purpose of this thesis, any paper that used the term surgical site infection and reviewed the relationship with regards to weight was included if the procedure met our definition of low risk. Of the 19 articles that met inclusion criteria, all were rated for quality using NIH Tools for cohort and case-controlled studies.

Chapter 4: Results

4.1 References Retrieved

A total of 329 papers were retrieved from CINAHL, Medline and EMBASE combined. Search results were merged and 30 duplicates were removed leaving a total of 299 documents. Of these, 253 articles were removed during title and abstract review based on defined exclusion criteria leaving 46 papers for which full text articles were retrieved. The reference review of the articles netted 12 additional papers that were included resulting in 58 full text articles that were reviewed. Both reviewers screened all papers for eligibility. Four papers were excluded by one reviewer. After discussion, the four papers were determined to meet inclusion criteria and were retained. Of the 58 full text articles reviewed, 39 were excluded and 19 articles met all eligibility criteria. Figure 4.1 shows the number of articles identified and reasons for exclusion.

The included studies were published between 1998 and 2015 (see Table 4.1). The studies were carried out in England, Japan, Scotland and the United States. All but one of the studies were undertaken in a hospital setting. Sample sizes ranged from 38 patients to 32,485 patients. Of the studies, 15 were cohort and four were case-control studies. Of these, six had matched the cases and controls or matched cohorts, and 13 were unmatched. Ten studies were prospective, six were retrospective and three used both retrospective and prospective methods.

Figure 4.1 Flowchart showing number of articles identified and reasons for exclusion

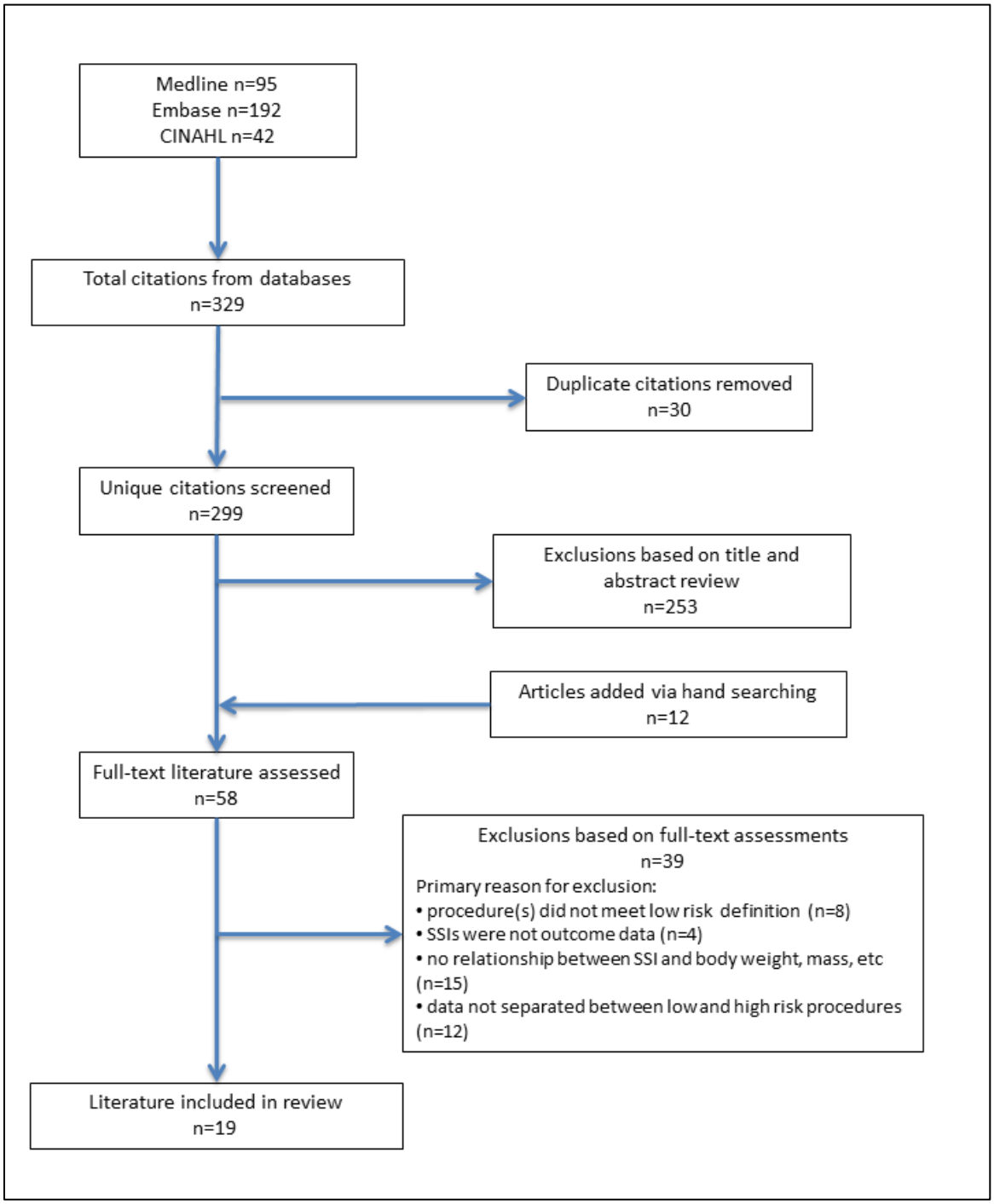

Table 4.1 Author, year and title of 18 articles identified in chronological order

	Authors	Title	Year
1	Winiarsky, R.; Barth, P.; Lotke, P.	Total knee arthroplasty in patients who are morbidly obese.	1998
2	Oliak, D.; Ballantyne, G.; Davies, R.; Wasielewski, A.; Schmidt, H.	Short-term results of laparoscopic gastric bypass in patients with BMI ≥60.	2002
3	Foran, J.; Mont, M.; Etienne, G.; Jones, L.; Hungerford, D.	The outcome of total knee arthroplasty in patients who are obese.	2004
4	Namba, R.; Paxton, L.; Fithian, D.; Stone, M.	Obesity and perioperative morbidity in total hip and total knee arthroplasty patients.	2005
5	Amin, A.; Clayton, R.; Patton, J.; Gaston, M.; Cook, R.; Brenkel, I.	Total knee replacement in patients who are morbidly obese: Results of a prospective, matched study.	2006
6	Amin, A.; Patton, J.; Cook, R.; Brenkel, I.	Does obesity influence the clinical outcome at five years following total knee replacement for osteoarthritis?	2006
7	Gould, J.; Garren, M.; Boll, V.; Starling, J.	Laparoscopic gastric bypass: Risks vs. benefits up to two years following surgery in patients who are super-super obese.	2006
8	Nemerofsky, R.; Oliak, D.; Capella J.	Body lift: an account of 200 consecutive cases in the massive weight loss patient.	2006
9	Chesney, D.; Sales, J.; Elton, R.; Brenkel, I.	Infection after knee arthroplasty: a prospective study of 1509 cases.	2008
10	Coon, D.; Gusenoff, J.; Kannan, N.; El Khoudary, S.	Body mass and surgical complications in the postbariatric reconstructive patient: Analysis of 511 cases.	2009
11	Malinzak, R.; Ritter, A.; Berend, M.; Meding J.; Olberding E.; Davis K.	Morbidly obese, diabetic, younger and unilateral joint arthroplasty patients have elevated total joint arthroplasty infection rates.	2009
12	Chen, S.; Anderson, M.; Cheng, W.; Wongworawat, M.	Diabetes associated with increased surgical site infections in spinal arthrodesis.	2009
13	Namdari, S.; Baldwin, K.; Glaser, D.; Green, A.	Does obesity affect early outcome of rotator cuff repair?	2010
14	Koutsoumbelis, S.; Hughes, A.; Girardi, F.; Cammisa Jr., F.; Finerty, E.; Nguyen, J.; Gausden, E.; Sama, A.	Risk factors for postoperative infection following posterior lumbar instrumented arthrodesis.	2011
15	Suzuki, G.; Saito, S.; Ishii, T.; Motojima, S.; Tokuhashi, Y.; Ryu, J.	Previous fracture surgery is a major risk factor of infection after total knee arthroplasty.	2011
16	Ballal, M.; Khan, Y.; Hastie, G.; Hatcher, A.; Coogan, S.; McNicholas, M.	Functional outcome of primary hamstring anterior cruciate ligament reconstruction in patients with different body mass index classes.	2013
17	Mehta, A.; Babu, R.; Sharma, R.; Karikari, I.; Grunch, B.; Owens, T.; Agarwal, V.; Sampson, J.; Shivanand, P.L.; Friedman, A.; Kuchibhatla, M.; Bagley, C.; Gottfried, O.	Thickness of subcutaneous fat as a risk factor for infection in cervical spine fusion surgery.	2013
18	Wallace, G.;Judge, A.; Prieto-Alhambra, D.; de Vries, F.; Arden, N.; Cooper, C.	The effect of body mass index on the risk of post-operative complications during the 6 months following total hip replacement or total knee surgery	2014
19	Alvi, H.M.; Mednick, R.E.; Krishnan, V.; Kwasny, M.J.; Beal M.D.; Manning D.W.	The Effect of BMI on 30 Day Outcomes Following Total Joint Arthroplasty.	2015

4.2 Surgery Types

Studies were grouped according to surgery type and procedure type in order to compare results. The surgical types were orthopaedics, neurosurgery, bariatrics and plastics and the procedure types were: 1) total knee arthroplasty (TKA) (i.e., total knee replacement) (Alvi, Mednick, Krishnan, & Kwasny, 2015; Amin, Clayton, et al., 2006; Amin, Patton, Cook, & Brenkel, 2006; Chesney, Sales, Elton, & Brenkel, 2008; Foran, Mont, Etienne, Jones, & Hungerford, 2004; Malinzak et al., 2009; Namba, Paxton, Fithian, & Stone, 2005; Suzuki et al., 2011; Winiarsky, Barth, & Lotke, 1998); 2) anterior cruciate ligament (ACL) and rotator cuff repair (RCR) (Ballal et al., 2013; Namdari, Baldwin, Glaser, & Green, 2010); 3) lumbar spinal surgery (LSS) (Chen, Anderson, Cheng, & Wongworawat, 2009; Koutsoumbelis et al., 2011; Mehta, Babu, Karikari, & Hughes, 2012); 4) laparoscopic Roux-en-Y gastric bypass (bariatrics) (Gould, Garren, Boll, & Starling, 2006; Oliak, Ballantyne, Davies, Wasielewski, & Schmidt, 2002); and 5) body lift (Coon, Gusenoff, Kannan, & El Khoudary, 2009; Nemerofsky, Oliak, & Capella, 2006). A summary of the surgical procedures, study design, country of origin and the healthcare setting(s) in which the research took place is presented in Tables 4.2 to 4.4.

Table 4.2 Articles reporting on orthopedic surgical procedures

Author, Year	Study design	Number of patients	Country	Healthcare setting	Setting type
Total Knee Replacements (total knee arthroplasty) (TKAs)					
Alvi et al., 2009	Prospective matched cohort	7950 knees in 5325 patients	USA	Northwestern Memorial Hospital, Chicago, Illinois	Hospital
Amin, Clayton et al., 2006	Prospective matched case-control	82 knees in 76 patients	Scotland	Queen Margaret Hospital, Dunfermline, United Kingdom	Hospital
Amin, Patton et al., 2006	Prospective unmatched cohort	328 knees in 283 patients	Scotland	Queen Margaret Hospital, Dunfermline, United Kingdom	Hospital
Chesney et al., 2008	Prospective unmatched cohort	1509 knees in 1349 patients	Scotland	Fife Acute Hospitals NHS Trust: Queen Margaret Hospital, Dunfermline, United Kingdom; Royal Infirmary of Edinburgh.	Hospital
Foran et al., 2004	Prospective matched case-control	156 knees in 126 patients	USA	The Good Samaritan Hospital, Baltimore, Maryland	Hospital
Malinzak et al., 2009	Prospective unmatched cohort	5719 knees	USA	The Center for Hip and Knee Surgery, St. Francis Hospital, Mooresville, Indiana.	Hospital
Namba et al., 2005	Prospective unmatched cohort	1813 knees	USA	Kaiser Permanente Orange County, Santa Ana, California; and Kaiser Permanente San Diego, California	Hospital
Suzuki et al., 2011	Retrospective unmatched cohort	2022 knees in 1146 patients	Japan	Affiliated hospitals of Nihon University School of Medicine	Hospital
Wallace et al., 2014	Retrospective and prospective unmatched cohort	32,485 patients	England	Affiliated hospitals contributing to Hospital Episode Statistics through the Clinical Practice Research Datalink database	Hospital
Winiarsky et al., 1998	Prospective matched case-control	1818 knees in 1579 patients	USA	Hospital of the University of Pennsylvania, Philadelphia	Hospital
Anterior Cruciate Ligament Repair (ACL repair)					
Ballal et al., 2013	Prospective matched cohort	92 patients	England	Warrington Hospital, NHS Foundation Trust	Hospital
Primary Rotator Cuff Repair (RCR)					
Namdari et al, 2010	Prospective unmatched cohort	154 patients	USA	Hospital of the University of Pennsylvania, Philadelphia, and Rhode Island Hospital, Providence, RI	Hospital

Table 4.3 Articles reporting on lumbar spinal surgery

Author, Year	Study design	Number of patients	Country	Healthcare setting	Setting type
Chen et al., 2009	Retrospective unmatched cohort	195 patients* analysis diabetic versus non-diabetic	USA	Loma Linda University Medical Center, Loma Linda, CA	Independent ambulatory surgical centre
Koutsoumbelis et al., 2011	Retrospective matched case control	252 patients	USA	Hospital for Special Surgery, New York, NY	Hospital
Mehta et al., 2012	Retrospective unmatched cohort	298 patients	USA	Duke University Medical Center, Durham, NC	Hospital

Table 4.4 Articles reporting on bariatrics and plastic surgery post-weight loss

Author, Year	Study design	Number of patients	Country	Healthcare setting	Setting type
Surgery for obesity (laparoscopic Roux-en-Y gastric bypass (LRNYGB)					
Gould et al., 2006	Retrospective review of prospectively maintained database unmatched cohort	288 patients	USA	University of Wisconsin Hospital and Clinics, Madison	Hospital
Oliak et al., 2002	Retrospective & prospective Unmatched cohort	300 patients (120 retrospective; 180 prospective)	USA	Hackensack University Medical Center, Hackensack, NJ	Hospital
Body lift					
Coon et al., 2009	Prospective unmatched cohort	511 procedures in 449 patients -194 single procedures, 317 multiple procedures	USA	Hospital of the University of Pennsylvania, Philadelphia	Hospital
Nemerofsky et al., 2006	Retrospective unmatched cohort	200 patients	USA	Meadowlands Hospital, Chapman Medical Center, and Hackensack University Medical Center, Hackensack, NJ	Hospital

4.3 Review of Studies

Studies were rated for quality using the appropriate NIH Tool for cohort or case-control research design (see Section 3.6: Data extraction and study quality assessment for a more detailed discussion). Results of individual studies were then classified by quality: Cohort studies were rated higher than case control; studies were rated higher if they used matching methods; and, studies were rated higher if they were prospective rather than retrospective. Only two papers indicated that they undertook a power analysis and met the required sample size (Ballal et al., 2013; Namdari et al., 2010). A power analysis increased the quality rating. If all other variables were equal, the studies were arranged in descending order by sample size. The reviewers disagreed on the grading for four studies, and these were resolved through discussion. See Table 4.5 for reviewers grading and discrepancies.

Table 4.5 Summary of quality of included studies

Author	Reviewer 1	Reviewer 2	Consensus
Cohort Studies			
Alvi	Fair	Fair	Fair
Amin, Patton	Poor	Poor	Poor
Ballal	Fair	Fair	Fair
Chen	Fair	Fair	Fair
Chesney	Good	Fair	**Good***
Coon	Poor	Poor	Poor
Gould	Fair	Poor	**Fair***
Malinzak	Good	Fair	**Good***
Mehta	Fair	Fair	Fair
Namba	Fair	Fair	Fair
Namdari	Good	Good	Good
Nemerofsky	Poor	Poor	Poor
Oliak	Good	Fair	**Fair***
Suzuki	Good	Good	Good
Wallace	Good	Good	Good
Case-control Studies			
Amin, Clayton	Fair	Fair	Fair
Foran	Fair	Fair	Fair
Koutsoumbelis	Good	Good	Good
Winiarsky	Fair	Fair	Fair

*Discrepancy resolved

There were six studies of good quality, 10 studies of fair quality, and three studies of poor quality. Table 4.6 provides a summary of study type as well as the quality of each study. The studies are listed in descending order of quality based on study design, sample size and whether or not power analysis was reported. The sample sizes identified in this summary were ascertained from the studies themselves. Some studies reported the population was based on patient counts, some reported number of surgeries, and some reported on both. An example of reporting on both is given in Suzuki's summary of 2,022 knees in 1,146 patients. Therefore over the study period there were 876 bilateral knee operations and 270 unilateral knee operations. Not all populations were delineated in this way, or it was not relevant to report number of patients separately from number of procedures (e.g., lumbar surgery). The method for reporting on sample population is captured in Table 4.6.

Table 4.6 Summary of study quality

Author, Year	Quality of Research	Study Type	Matching	Prospective/ Retrospective	Sample
Wallace et al., 2014	Good	Cohort	Unmatched	Retrospective and prospective	32,485 patients; number of knees not reported
Malinzak et al., 2009	Good	Cohort	Unmatched	Prospective	5719 knees; number of patients not stated
Chesney et al., 2008	Good	Cohort	Unmatched	Prospective	1509 knees in 1349 patients
Namdari et al., 2010	Good	Cohort	Unmatched	Prospective	154 patients*, rotator cuff repairs
Suzuki et al, 2011	Good	Cohort	Unmatched	Retrospective	2,022 knees in 1,146 patients
Koutsoumbelis et al., 2011	Good	Case Control	Matched	Retrospective	252 patients, lumbar spine
Alvi et al., 2015	Fair	Cohort	Matched	Prospective	7950 knees in 5325 patients
Namba et al., 2005	Fair	Cohort	Unmatched	Prospective	1813 knees; number of patients not stated
Gould et al., 2006	Fair	Cohort	Unmatched	Prospective	288 patients, Roux-en-Y
Ballal et al., 2013	Fair	Cohort	Unmatched	Prospective	92 patients*, ACL repairs
Oliak et al., 2002	Fair	Cohort	Unmatched	Retrospective	300 patients, Roux-en-Y
Mehta et al., 2012	Fair	Cohort	Unmatched	Retrospective	298 patients, lumbar spine
Chen et al., 2009	Fair	Cohort	Unmatched	Retrospective	195 patients, lumbar spine
Foran et al., 2004	Fair	Case Control	Matched	Prospective	156 knees in 126 patients
Winiarsky et al., 1998	Fair	Case Control	Matched	Prospective	1818 knees in 1579 patients
Amin, Clayton et al., 2006	Fair	Case Control	Matched	Prospective	82 knees in 76 patients
Coon et al., 2009	Poor	Cohort	Unmatched	Prospective	511 body lifts in 449 patients
Amin, Patton et al. 2006	Poor	Cohort	Unmatched	Prospective	328 knees in 283 patients
Nemerofsky et al., 2006	Poor	Cohort	Unmatched	Retrospective	200 patients, body lifts

***undertook and met power analysis**

4.4 Variability Across Studies

According to Higgins et al. (2003) diversity in methodological aspects should be investigated as part of an investigation of variability across studies (Higgins, Thompson, Deeks,

& Altman, 2003). Heterogeneity of surgical site infection and obesity cutoff points are presented next.

4.4.1 Definitions for Surgical Site Infections

Three studies used the common CDC/HICPAC definitions to determine SSI numbers or rates, four papers had unique definitions and 11 studies used terms that were not defined. The summary of the findings from reviewing the SSI definitions are presented in Table 4.7. How SSIs were reported presents additional complexity for data comparison because SSIs were not reported homogenously. Although U.S.-CDC defines three levels of infections; superficial, deep incisional and organ space, research often combines the final two into a single "deep" designation. Five studies separated infections into superficial or deep (S or D), 11 studies grouped the results and reported all infections, and three studies reported deep infections only (See Table 4.7).

Table 4.7 Classification of surgical site infection definitions across studies

Author, Year	Superficial	Deep	Separate or Grouped
I. CDC definition (n=3)			
Chen et al., 2009	Uses CDC/HICPAC definitions	Uses CDC/HICPAC definitions	Grouped
Koutsoumbelis et al., 2011	Uses CDC/HICPAC definitions	Uses CDC/HICPAC definitions	Grouped
Mehta et al., 2012	Uses CDC/HICPAC definitions	Uses CDC/HICPAC definitions	Grouped
II. Unique definition: separate results (3)			
Chesney et al., 2008	CDC 1988 (unique)	Deep infection was counted as an infection that required a secondary procedure.	Separate
Amin, Clayton et al., 2006	Unique definition: Superficial if it resolved with oral antibiotics	Unique definition: Deep if a re-operation or revision procedure was required.	Separate
Amin, Patton et al. 2006	Unique definition: Superficial if it resolved with oral antibiotics	Unique definition: Deep if a re-operation or revision procedure was required.	Separate
III. Unique definition: grouped results (n=3)			
Namba et al., 2005	Unique definitions – Superficial infection cases were defined as wound drainage or erythema, which required intravenous antibiotics which prolonged hospital admission or required readmission for management with intravenous antibiotics. Superficial cellulitis (wound erythema) managed with oral antibiotics on an outpatient bases was not recorded as infection.	Unique definitions – Any infection treated operatively or any positive culture was considered a deep infection.	Grouped
Oliak et al., 2002	Unique definition – Minor wound, within 30 days of surgery, major wound after 30 days		Grouped
Winiarsky et al., 1998	Unique definition – Within 20 weeks of surgery separation of the skin margins with prolonged drainage necessitating an alteration in the normal postoperative course – does not differentiate between superficial and deep definitions		Grouped
IV. No definition provided: separate results (n=2)			
Alvi et al., 2015	Not defined	Not defined	Separate
Ballal et al., 2013	Not defined	Not defined	Separate

Note: Separate – Deep and superficial separated into two distinct categories
Grouped – Deep and superficial infection rates reported as a grouped value

Table 4.7 Classification of surgical site infection definitions across studies (cont'd)

Author, Year	Superficial	Deep	Separate or Grouped
V. No definition provided: grouped results (n=5)			
Coon et al., 2009	Not defined	Not defined	Grouped
Foran et al., 2004	Not defined	Not defined	Grouped
Gould et al., 2006	Not defined	Not defined	Grouped
Nemerofsky et al., 2006	Not defined	Not defined	Grouped
Wallace et. Al., 2014	Not defined	Not defined	Grouped
VI. No definition provided: only reported on deep infections (n=3)			
Suzuki et al, 2011	Not defined or reported on	Not defined	Only deep infections reported
Malinzak et al., 2009	Not defined or reported on	Not defined	Only deep infections reported
Namdari et al., 2010	Not defined or reported on	Not defined	Only deep infections reported

Note: Separate - Deep and superficial separated into two distinct categories
Grouped - Deep and superficial infection rates reported as a grouped value

Because of the variations of definitions and discrepancies in reporting SSI results, few papers could be synthesized. Papers that used the "other definition" of SSI were compared to determine if the definitions were similar enough to compare to each other. None of the unique definitions were homogenous and therefore could not be compared. The only results that could be compared were in the three papers that use the standard CDC definition. All three papers examined the impact of BMI on lumbar spine surgeries (Chen et al., 2009; Koutsoumbelis et al., 2011; Mehta et al., 2012).

4.4.2 Obesity Classification

All studies used BMI as the indicator for obesity although one paper embedded the BMI classification of 'overweight' into the obese cohort (Ballal et al., 2013). One of the papers that reported on lumbar spinal surgery also reviewed the lamina to the skin depth at the fourth lumbar

vertebra, and the subcutaneous fat depth at the surgical site to compare results to BMI obesity cutoff (Mehta et al., 2012). One paper used maximum BMI (before surgery) and change in BMI (pre-surgery BMI minus current BMI) as well as current BMI for comparison (Coon et al., 2009).

Stratification of BMI and the definition for obesity in the identified articles were heterogeneous. One paper merged its obesity cohort with data from patients who are not obese (Ballal et al., 2013). Six studies did not specify weight ranges for BMI categories (Chen et al., 2009; Chesney et al., 2008; Koutsoumbelis et al., 2011; Malinzak et al., 2009; Mehta et al., 2012; Namba et al., 2005). Three studies used obesity definitions unique from the other 15 studies (Coon et al., 2009; Nemerofsky et al., 2006; Suzuki et al., 2011). Four studies reviewed Obesity-Class I groupings (Amin, Patton, et al., 2006; Foran et al., 2004; Namdari et al., 2010; Wallace et al., 2014), four studies reviewed Obesity-Class III ± 40 kg/m^2 cohorts (Alvi et al., 2015; Amin, Clayton, et al., 2006; Foran et al., 2004; Winiarsky et al., 1998), and two studies reviewed Obesity-Class III ± 60 kg/m^2 cohorts (Gould et al., 2006; Oliak et al., 2002). Of the eight studies that used Obesity-Class I-III classifications, the comparator groups were all different; therefore the published results could not be compared. While it is possible that the raw data may have been useful for this systematic review, this information was not sought from the authors.

For a complete review of BMI and obesity stratifications and differences in SSI rates between groups, see Table 4.8.

Table 4.8 Differences in SSI rates between groups based on obesity classifications

Study authors and year Surgery type Total Sample Size (number of procedures)	Study Quality	BMI comparison groups (kg/m^2) Mean (Range) Obesity Classification (WHO)	N in each cohort Patients (number of procedures)	Number/rate of infections (%) or (RR) [95% CI]	*p*-value	Results
Heaviest comparator group Obese Class I (≥ 30 kg/m^2) versus non-obese (<30 kg/m^2)						
Amin, Patton et. al, 2006 TKA 283 (328)	Poor	<30 26.3 [standard deviation 2.3] Normal to overweight	158 (181)	S 6 (2.8) D 2 (0.9)	≥ 0.05	Although the rate of superficial SSIs was higher in the obese cohort (>30 kg/m^2), the difference was not statistically significant. The rate of deep SSIs was lower in the obese cohort and this difference was also not statistically significant.
		>30 34.2 [SD 3.1] Obese Classes I and II	125 (147)	S 7 (4.3) D 1 (0.6)		
Foran, et. al., 2004 TKA 126 (156)	Fair	<30 (17.6-29.8) Underweight, normal weight and overweight	68 (78)	A 1 (1.3)	=1.00	In the two matched cohorts (obese versus non-obese), the rates of SSI were equal. Although a sub-group analysis of patients who are morbidly obese (> 40 kg/m^2) was undertaken, the results were not reported in this study. An additional complication with these results is that the non-obese group included patients who were underweight; poorly nourished patients are at a greater risk for infections.
		≥30 (30-47) Obese Classes I, II, and III	68 (78)	A 1 (1.3)		
Namdari et.al., 2010 RCR 154	Good	≤ 30 25.5 Unspecified weight range Not obese	97	A 1 (1.0)	No *p*-values reported	Although the rate of SSIs in the obese group was almost four times higher than in the non-obese group, the authors report that they lacked sufficient power to detect a statistically significant difference between groups.
		>30 33.3 Unspecified weight range Obese, unknown class(es)	57	A 2 (3.5)		
Wallace et.al., 2014 TKA 32,485	Good	< 30 (18.5-25) Normal weight	5396	145 (1.6)	REF	Patients with a BMI <30 kg/m^2 have an increased risk of wound infection compared to patients who are normal weight.
		>30 30-35 Obese, Class I	9272	173 (2.5) 1.52 [1.21-1.90]	<0.001	
		>30 35+ Unknown weight range Obese, > Class I	5276	103 (3.5) 2.18 [1.67-2.86]	<0.001	

NOTE: S=superficial infection; D=deep infection; A=all infections; TKA=Total Knee Arthroplasty; RCR = rotator cuff repair

Table 4.8 Differences in SSI rates between groups based on obesity classifications (con't)

Study authors and year Surgery type Total Sample Size (number of procedures)	Study Quality	BMI comparison groups (kg/m^2) Mean (Range) Obesity Classification (WHO)	N in each cohort Patients (procedures)	Number/rate of infections (%) or (RR) [95% CI]	*p*-value (Relative risk) [odds ratio]	Results
Heaviest comparator group Obese Class III (≥ 40 kg/m^2) versus non-Obese Class III						
Alvi, et. al, 2015 TKA for osteoarthritis 5325 (7950)	Fair	< 25 (18.5 -25) Normal weight	1775 (2650)		See Results column	Patients with a BMI > 40 kg/m^2 were more likely than patients with a normal BMI to present with a superficial SSI (p=0.024). Additionally, patients with a BMI > 40 kg/m^2 were more likely than patients who were overweight to get either superficial (p=0.007) or deep wound infections (p=0.007) all results were statistically significant
		(25-30) Overweight	1775 (2650)	S (RR 0.58) [0.13-1.45] D (RR 0.33 [0.03-3.32]		
		> 40 Obese Class III	1775 (2650)	S (RR 1.98) [0.62-6.33] D (RR 1.12) [0.22-5.57]		
Amin, Clayton et.al., 2006 TKA 76 (82)	Fair	<30 (22.8-29.7) Normal and overweight	38 (41)	S 0 D 0	None reported	Patients who are morbidly obese had higher rates of superficial and deep SSIs than the non-obese group (authors report statistical significance but did not give p value)
		>40 (40.1-61.3) Obese Class III	38 (41)	S 7 D 2		
Chesney et.al., 2008 TKA 1349 (1509)	Good	<40 Unspecified weight range Unknown classification	(1244)	S 45 (3.6) D 15 (1.2)	$p \geq 0.05$	The differences in SSIs between patients with a BMI > 40 kg/m^2 (morbidly obese, Obese Class III) and those not morbidly obese did not achieve statistical significance.
		>40 Obese Class III	(34)	S 3 (8.8) D 1 (2.9)		
Malinzak et.al., 2009 TKA (5719)	Good	<40 Unspecified weight range Unknown classification >40 Obese Class III	7521 (hip and knee)	A 35 (<1)	p = 0.0045	Infection rates for both hip and knee surgeries were reported, knee surgery results were not reported separately. Patients with a BMI > 40 kg/m^2 had 3.3 times greater odds of getting a deep SSI than patient with BMI < 40 kg/m^2 and this difference was statistically significant.
		>40 Obese Class III	490 (hip and knee)	A 8 (1.6)		

NOTE: S=superficial infection; D=deep infection; A=all infections; TKA=Total Knee Arthroplasty

Table 4.8 Differences in SSI rates between groups based on obesity classifications (con't)

Study authors and year Surgery type Total Sample Size (number of procedures)	Study Quality	BMI comparison groups (kg/m^2) Mean (Range) Obesity Classification (WHO) Other measurements	N in each cohort Patients (procedures)	Number/rate of infections (%) or (RR) [95% CI]	*p*-value	Results
Heaviest comparator group Obese Class III (≥ 40 kg/m^2) versus non-Obese Class III (cont'd)						
Winiarsky et.al., 1998 TKA 1579 (1818)	Fair	≤40 (10.9-39.7) Underweight, normal, overweight and Obese Classes I and II	1539 (1768)	A 11(<1)	*p* < .0001	Patients who were morbidly obese had higher rate of SSIs than patients who were not morbidly obese. Confounding factors: The non-obese group included patients who were underweight which may underestimate the risk of obesity in the morbidly obese cohort since poorly nourished patients are also at a greater risk for infections. Additionally, patients were treated with a pre-operative antibiotic regime that was not described. If dosing was not weight-based, then the antibiotics may skew the results in favour of the patients with lower weights.
		>40 (40.3-56.2) Obese Class III	40 (50)	A 5 (10)		
Heaviest comparator group Obese Class III+ (≥ 60 kg/m2) versus Class III <60 kg/m2						
Gould et. al., 2006 LRNYGB 288	Fair	<60 48.3 (± 5.4) Obese Class III	260	A 6 (2.3)	*p* =0.68	No difference in rates of SSIs
		≥ 60 62.0 (± 2.3) Obese Class III +	28	A 1 (3.6)		
Oliak et. al., 2002 LRNYGB 300	Fair	<60 36-59 Obese Classes II and III	261	Major 1 Minor 15	Not reported	Authors reported that the study "did not have the power to detect small differences in complications."
		≥ 60 60-86 Obese Class III+	39	Major 0 Minor 6		

NOTE: S=superficial infection; D=deep infection; A=all infections; TKA=Total Knee Arthroplasty; LRNYGB= Laparoscopic Roux-en-Y Gastric Bypass.

Table 4.8 Differences in SSI rates between groups based on obesity classifications (con't)

Study authors and year Surgery type Total Sample Size (number of procedures)	Study Quality	BMI comparison groups (kg/m^2) Mean (Range) Obesity Classification (WHO) Other measurements	N in each cohort Patients (procedures)	Number/rate of infections (%) or (RR) [95% CI]	*p*-value	Results
Unique obesity classifications						
Mehta et.al., 2012 Lumbar spine 298	Fair	<30 Unspecified weight range Not obese	176	A 9 (5.1)	= 0.025	Sub-analysis showed that patients who were obese (BMI ≥30 kg/m2) are at statistically significant higher risk for SSIs than patients who were not obese (BMI<30kg/ m2) The results demonstrate the difference in means in BMIs between the SSI group versus the non-SSI group were not significant. Additionally, as skin to lamina depth and thickness of subcutaneous fat increased, the risk of infection also increased. [1.037; 95% CI 1.007-1.068]
		≥30 Unspecified weight range Obese, unknown class(es)	122	A 15 (12.3)		
		SSIs - BMI mean (30.9 kg/m^2)	24	N/A	= 0.12	
		non-SSIs –BMI mean (28.9 kg/m^2)	274	N/A		
		SSIs - Lamina to skin mean (74.8 mm)	24	N/A	= 0.046	
		non-SSIs - Lamina to skin mean (67.4 mm)	274	N/A		
		SSIs - Subcutaneous fat depth at level of surgery mean (30.2 mm)	24	N/A	= 0.035	
		non-SSIs - Subcutaneous fat depth at level of surgery mean (23.9 mm)	274	N/A		
Koutsoumbelis et. al., 2011 Lumbar spine 252	Good	SSI group obese ≥30 Unspecified weight range unknown class(es)	84	A 36 of 84 patients were obese (42.9)	= <0.001	After adjusting for all other variables, obesity was determined to have the strongest association for SSI development of any of the risk factors analyzed [RR=9.75; 95% CI 4.70 - 20.21]
		Non-SSI group (two randomly selected matched controls) obese ≥30 Unspecified weight range unknown class(es)	168	A 12 of 168 patients were obese (7.1)		
Namba et.al., 2005 TKA (1813)	Fair	≤35 27 (4) Unspecified weight range but less than Obese Class II	1391	A 4 (0.03)	= 0.01	The differences in SSI rates reached statistical significance when comparing patients > 35 kg/m2 with patients ≤ 35 kg/m2
		>35 39.5 (34) Obesity Classes II and III	422	A 5 (1.2)		

NOTE: S=superficial infection; D=deep infection; A=all infections; TKA=Total Knee Arthroplasty

Table 4.8 Differences in SSI rates between groups based on obesity classifications (con't)

Study authors and year Surgery type Total Sample Size (number of procedures)	Study Quality	BMI comparison groups (kg/m^2) Mean (Range) Obesity Classification (WHO) Other measurements	N in each cohort Patients (procedures)	Number/rate of infections (%) or (OR or RR) [95% CI]	*p*-value	Results
Unique obesity classifications (cont'd)						
Chen et.al., 2009 Lumbar spine 195	Fair	≤35 Unspecified weight range but less than Obese Class II	165	A RR=1.864 [95% CI 0.810-4.287],	No *p*-values reported	No difference in rates of SSIs
		>35 Obesity Classes II and III	30			
Nemerofsky et.al., 2006 Body lifts 200	Poor	≤32 Unspecified weight range but less than Obese Class II	153	A 6 (3.9)	No *p*-values reported	Unable to determine relationship; no p-values and statistical significance were reported.
		>32 Unspecified weight range unknown class(es)	47	A 4 (8.5)		
Coon et.al., 2009 Body reconstructions 449 (511)	Poor	Max BMI (BMI before weight loss) <50	Not reported	A – (OR=2.6); [95% CI 1.28-5.39]	*p* = 0.003	Patients with maximum BMI >50kg/m^2 had a 2.6 times greater odds of developing an SSI than patient with a max BMI <50 kg/m^2. The authors did not report raw numbers or rates.
		Max BMI (BMI before weight loss) >50	Not reported			
Suzuki et.al., 2011 TKA 1146 (2022)	Good	Mean BMI 27.4 (±5.5)	17 (17)	A – (OR = 1.2) [95%CI 1.0-1.3]	*p* = 0.007	The difference in BMI between the infected and uninfected cohorts was not statistically significant. Stepwise logistic regression analysis identified BMI was a risk factor for the development of SSI
		Mean BMI 25.6 (±4.1)	1257 (2202)			
Ballal et.al., 2013 ACL 92	Fair	<25 22.56 (18.5-24.99) Normal weight	49	S 0 (0) D 1 (2.0)	No *p*-values reported	Unable to determine relationship; the authors reported rates of infection only and did not conduct statistical analysis of the raw numbers
		≥25 29.67 (25.38-39.61) Overweight, Obese Classes I and II	43	S 2 (4.7) D 1 (2.3)		

NOTE: S=superficial infection; D=deep infection; A=all infections; TKA=Total Knee arthroplasty; ACL= Anterior Cruciate Ligament repair

4.4.3 Surgical Site Infections and Body Mass Index Synthesis

Upon review of the three references identified as homogenous in the SSI definition grouping, only the studies by Koutsoumbelis, et al. and Mehta et al. had comparable BMI categories, <30 kg/m² (non-obese) and ≥30 kg/m² (obese). These two articles both determined that obesity (BMI ≥30 kg/m²) carried a significant risk for SSIs after lumbar surgery.

The Koutsoumbelis study was a good quality, retrospective, matched, case control study (Koutsoumbelis et al., 2011). The patient demographics of the group with SSIs were matched with a cohort of two randomly selected control subjects to minimize confounders. This study used a validated definition for SSIs and the BMI measurement for obesity was also an internationally accepted cutoff point. The results of this article identified that obesity, defined as a body mass index of ≥30 kg/m²) had the strongest association for SSI development of all risk factors analysed.

The study type undertaken by Mehta et.al. (2013) was a retrospective, unmatched, cohort design. The study quality for the Mehta study was rated as fair because of key gaps in the information reported. One gap was that how researchers followed up with patients (i.e., whether the follow-up was passive and patient-driven versus proactive) was not described. Additionally, confounders were not described in full nor did the authors statistically adjust for them. Despite identifying multifactorial patient risk factors for SSIs, including tobacco and alcohol use, previous spine surgery and the presence of more than three comorbidities, the only identified and reported confounders were age, gender, BMI/obesity and diabetes. Obesity (BMI ≥ 30 kg/m²) was identified as a significant risk factor for SSIs (p=0.025). As patient follow-up was not described, it is unclear how SSIs were identified and diagnosed and therefore SSIs could be under-reported. Additionally, this article did not adjust for identified confounders. Therefore

there is no confidence that the information provided was free from bias. Not adjusting for confounding factors may falsely demonstrate an association between the treatment and outcome when no actual association exists (Skelly, Dettori, & Brodt, 2012).

4.5 Conclusion

The 19 research studies reported on six types of low risk surgeries: total knee arthroplasty (TKA), rotator cuff repair (RCR), anterior cruciate ligament repairs (ACL), lumbar spine surgery (lumbar), laparoscopic Roux-en-Y gastric bypass (LRNYGB) procedure for weight reduction (bariatrics) and body lifts (plastics). Of these 19 papers, most were cohort studies (n=15) and four were case-control studies (n=4). The quality of the studies were classified as good, fair and poor (n=6, n=10 and n=3 respectively) using the NIH Quality Tools for cohort or case-control research design.

There was a lot of variability in working definitions for both SSIs and obesity. For definitions of SSIs, only three papers followed the US-CDC definitions, five papers had unique definitions, and 11 papers did not define SSIs. Additionally, of the 19 papers, five papers divided SSIs into deep and superficial categories, 11 papers either grouped results into all infections or did not describe the categorizations, and three papers reported on deep infections only.

Another variation in working definitions was for the measurement of obesity. Although all 19 studies used BMI for defining obesity, two studies had additional measurements; one used maximum BMI, current BMI and change in BMI, and one used lamina and subcutaneous fat depth. Additionally, one study used a unique cutoff point of 32 kg/m^2 to define obesity and one study compared the BMIs of infected versus non-infected cohorts. Of the 19 studies included,

none used the same cutoff points and comparator ranges and therefore, due to the heterogeneity of the research definition and variability of study quality, none of the results could be pooled.

Ten out of 19 studies found there was a statistical difference in SSI rates for patients with obesity, six studies found no difference, and three studies either lacked power to complete the analysis or did not report their results. Analyzing the results of specific surgical procedures, 6 of 10 total knee arthroplasty papers, 2 of 3 lumbar papers and 1 of 2 body lift articles found a statistical significance between patients that were measured to have some degree of obesity and those that were not obese. Therefore, there appears to be some evidence from studies of varying quality that suggests that obesity is associated with SSIs in TKAs, lumbar spine surgery and body lifts.

Chapter 5: Discussion

5.1 Introduction

A systematic review is an approach designed to address volumes of published literature with the aim of synthesizing the findings to determine overall impact and relevance of multiple results (Littlewood, Ashton, Chance-Larsen, & May, 2012). The purpose of this thesis was to conduct a systematic review to examine if obesity increased the risk for post-operative surgical site infections (SSIs) for patients undergoing low risk surgeries. Only two studies used comparable definitions for both SSI and obesity. These two studies found that patients undergoing lumbar surgery with a BMI $\geq 30 kg/m^2$ were at higher risk for SSIs, but one study was of poor quality, therefore these results could not be pooled. The rest of the studies used a variety of definitions for either SSIs and/or weight classifications and these too were unable to be pooled. However, when analyzing the studies that found statistical significance in SSI rates for patients with obesity, it appears that obesity is likely associated with SSIs in TKAs, lumbar spine surgery and possibly body lifts. Research that analyzed RCR (one paper), ACL (one paper) and R-en-Y surgeries (two papers) did not find statistical significance, however, due to the few numbers of each procedure that met inclusion criteria and therefore included in this paper, concluding that obesity was not a risk factor for those procedures would be imprudent.

5.2 Inclusion Criteria, Studies Identified and Quality Assessment

Articles were included if SSI was reported as an outcome and if obesity was a risk factor. Because of the variable use of definitions for both SSI and obesity, all definitions were included. Articles were also included if they met the criteria for low risk surgical procedures using

admission inclusion and exclusion criteria for outpatient surgeries. Only the published results were reviewed; no authors were contacted to request raw data or to request data that could be separated (i.e., several papers presented merged data of both low risk and other risk surgeries). Nineteen articles met inclusion criteria. Eighteen of these 19 articles were carried out on inpatients from hospital settings; one article captured data from an ambulatory surgical centre (ASC).

Of the included articles, there were no meta-analyses, systematic reviews or randomized control studies found, only cohort (n=14) and case-controlled studies (n=4). Although case-control and cohort studies measure disease occurrence and its association with an exposure through the dimension of time (i.e., prospective or retrospective study design), they do not measure causal relationships and therefore internal validity is not high (Trochim, 2006). Case-control studies are usually placed low in the hierarchy of evidence as they are often retrospective. Information about the patient's exposure may be lacking, potentially introducing bias. However, in the case of SSIs, a surgery must have occurred and therefore a case-control study is relatively equal to a retrospective cohort study and were considered acceptable for this PICO question (Khan, Kunz, Kleijnen, & Antes, 2011).

This systematic review undertook an assessment of the articles to determine their quality as "a key component of the systematic review process is an assessment of study quality or risk of bias" (The Cochrane Collaboration, 2011). When assessing study quality in systematic reviews and meta-analyses, experts recommend at least two independent reviewers rate each study, in an attempt to ensure inter-rater reliability an essential attribute of the assessment (Khan et al., 2011). Two independent reviewers evaluated all studies at every step in this systematic review. The results for each question were used to assess flaws in study design or implementation to

identify any risk of bias that may have occurred. For example, a review of which confounders were adjusted for was undertaken to ensure the risk of obesity on SSIs could be explicitly identified in each study as per best practices for avoiding biases in observational studies (Hammer, du Prel, & Blettner, 2009). For this rating, the NIH Quality Tools for cohort or case-control research design were used. These tools rank studies into three categories; good, fair and poor. As described by the developers of the tool, "a good study has the least risk of bias, and results are considered to be valid…a fair study is susceptible to some bias deemed not sufficient to invalidate its results…a poor study indicates significant risk of bias (para. 6)" (U.S. Department of Health & Human Services, 2014a). The fair quality category is likely to have the largest group of studies, so papers within this rating vary in their strengths and weaknesses and were measured against the other studies in this category. Poor quality studies were included in this systematic review as there were very few studies of higher quality. The final result estimation of the quality of the nineteen papers were that six articles were determined to be good, ten studies were fair and three papers were assessed to be poor quality. Given that the final results were unable to be synthesized because of the heterogeneity of definitions and outcomes, inclusion of poor quality studies had no effect on the conclusions.

5.3 Variability of the Definition of Surgical Site Infection

It is important to ensure that quality measures and their risk-stratification variables are accurate and reliable (U.S. Agency for Healthcare Research and Quality, 2016); homogeneous definitions assure meaningful measurement and comparisons. Shared definitions for the diagnosis of SSI were critical to compare outcomes across the studies. The definition of SSI from the U.S. Centers for Disease Control (CDC) is the most comprehensive and most widely

used within healthcare research literature (Leaper, Tanner, & Kiernan, 2013). Unfortunately, only three studies included in this review used this definition. Heterogeneous clinical criteria to define SSI made it difficult to compare results across studies. This is problematic because data found within the research papers can only be compared if working definitions for data collected are equivalent (U.S. National Research Council (US-NRC) of the National Academies, 2013). Use of standardized definitions for SSIs as well as similar or adjusted variables would allow comparison of infection rates; this is beneficial because comparisons improve data accuracy and usefulness (Macbeth, Gardner, Wallis, & Gerrard, 2005). Therefore, future research should consider using the most recent definitions as a key part of a study.

5.4 Variability of Definitions of Obesity and BMI

The cutoff points for BMI between comparison groups also varied throughout the included research papers. Although six of the nineteen studies used the WHO cutoff value of 30 kg/m^2, the comparator groups were heterogenous, so the results were inconsistent and difficult to compare.

Although BMI is a widely accepted measure, it does not provide a direct measure of body fat, nor provide information about the distribution of fat, and it does not distinguish between excess fat, muscle, or bone mass (Health Canada, 2003). Furthermore, BMI may not be a predictor of obesity for people who are still growing, have extremes of height or fall within some ethnic groups (Health Canada, 2003). The distribution of the excess weight might play a more significant role in determining obesity than BMI; excess abdominal fat (central or visceral obesity) has a greater association with mortality and comorbid disease conditions than generalized fat stores (Ardern, Katzmarzyk, Janssen, & Ross, 2003; Després, 2012; Health

Canada, 2003; Shields, Tremblay, Connor Gorber, & Janssen, 2012). Although it is the easiest and most cost effective measurement to take, it is likely that BMI does not accurately reflect post-operative risks including SSIs. Obesity is known to be a risk factor for SSIs. As new research is undertaken, it is crucial for researchers to determine accurate measurements for obesity and body weight that are cost effective, easy to use, and accurate which can be adopted widely.

5.5 Obesity, Low Risk Surgical Procedures and SSIs

Obesity is commonly identified as a risk factor for SSIs. In the absence of reliable and analogous definitions, direct comparisons cannot to be made, thereby weakening attempts at meta-analyses. This systematic review did not find enough comparable data in published research to make a determination if obesity as a risk factor for surgical site infections holds true for a sub-set of low risk surgeries. This finding does not discount earlier meta-analyses that found obesity carries a significant risk for SSIs post-operatively, it simply identifies that not enough information was found during this review to inform decision-making for low risk surgical procedures. Future research is required that specifically examines obesity risk for SSIs in low risk procedures.

5.6 Considerations for Patient Safety Initiatives

There has been an explosion of publications on patient safety in the last two decades (Lilford, Stirling, & Maillard, 2006). Patient safety initiatives begin with recognition of the need for an intervention to improve patient safety usually through trends in surveillance of adverse events (Shojania, 2008). Given that infections are rated as the third leading cause of adverse

events in healthcare (Classen et al., 2011; World Health Organisation, 2009), they should be considered a priority for patient safety. Greater attention is required to under-researched surgical populations such as low risk patients who undergo surgical procedures, especially in outpatient settings.

5.7 Considerations for Outpatient Surgical Settings

Although the frequency of outpatient surgery has grown worldwide there is a shortage of outcome data for patients undergoing low risk procedures. As of 2012 the majority of low risk surgeries were performed in an outpatient setting. In addition, the number of people having elective surgery has increased; merged data from the United States (U.S.) and Canada shows that annual plastic surgery volumes have risen approximately 725% between 1992 and 2005 (The American Society for Aesthetic Plastic Surgery, 2016); bariatric surgery has increased from approximately 158,000 cases in 2011 to 196,000 cases in 2015 (American Society for Metabolic and Bariatric Surgery, 2016); and elective knee replacements are expected to rise 673% between 2006 and 2026 (American Association of Orthopaedic Surgeons, 2006). As more low risk surgeries are being undertaken in outpatient surgical settings, this type of facility might be able to be used as a source for information for low risk surgery risk factors and outcomes.

5.8 Limitations of Design

This study has several limitations. Firstly, no attempt was made to contact researchers who had merged data. Many studies that merged data from higher risk procedures with lower risk procedures were excluded (e.g., total knee and total hip arthroplasties were often reported using combined data). No attempt was made to obtain data that could have been reported separately (i.e., total knee arthroplasty data may have been available individually). If

disaggregated data had been obtained, the additional results might have impacted the conclusions found in this study. In addition, no attempts were made to contact researchers to request missing data (i.e. p-values) or raw data for independent analysis. Best practice for systematic reviews suggests that reasonable attempts to contact study authors should be made in order to enable a full assessment of study quality rather than just an assessment of report writing (Littlewood et al., 2012). Secondly, this analysis was based on a limited number of studies, several of which have modest sample sizes. Compared to a review with a larger overall sample size, this study is less likely to detect statistically significant differences. Thirdly, during the systematic review, only published studies were evaluated. Grey literature was not searched. A systematic review published in 2008 found that grey literature, which often reports more negative or inconclusive data than published journal articles, can affect the outcome of a review and may overcome publication bias (Hopewell et al., 2008). Therefore, this systematic review is open to selection bias and publication bias.

5.9 Implications for Nursing Practice

Nurses must be able to voice their concerns in a manner that can be heard in order to optimize patient safety (Marshall & Zolnierek, 2012). Because of nurses' proximity and continuity with patients, nurses are often able to identify conditions that may result in near misses or adverse events. Nurses have important advocacy roles to ensure safety in surgical services, performing activities such as pre-operative assessments, perioperative evaluations and post-operative teaching. Therefore nurses play a pivotal role in influencing patient-centred care and maximizing the impact of patient safety initiatives.

Definitive outcomes for the risk of SSIs related to obesity in low risk surgeries were not established in this literature review because of the variability of definitions for both SSIs and obesity. In order to improve clinical practice, future research should ensure precise definitions of SSIs, and strive for more accurate measurements of obesity.

Although obesity, as defined by BMI does not automatically mean lower body mobility problems or health complications, the risks of both increase as people become heavier (Grundy & Barnett, 1990; Vincent, Vincent, & Lamb, 2010). This amplified risk translates into growing numbers of patients seeking healthcare for weight-related problems. As the incidence of patients who are obese and who are seeking healthcare continues to rise, policies and procedures must be created or adapted to meet the unique needs of this population to maintain their safety (Hammond, 2013). In the surgical setting, given that the nurse is responsible to ensure safe patient care occurs, pre-operative education should include appropriate potential weight-related risks for the procedure the patient is about to undertake. Further, ensuring obesity-specific post-operative education is provided, understood and the patient is capable or has appropriate support to achieve the recommendations for post-op care is imperative.

5.10 Implications for Policy

Developing policy for the patients who are obese should become part of all healthcare practice. As health policy needs high quality evidence to inform care of patients who are obese and who are undergoing low risk procedures, policy makers could contribute to this evidence base through focused research and evaluation of any low risk procedures being conducted on patients who are obese.

5.11 Implications for Research

Although the relationship between SSIs and obesity has been established in the literature, we did not identify definitive evidence linking SSI rates to obesity. Due to heterogeneity of SSI and obesity definitions, and the variability in the use of BMI cutoff points, a relationship between obesity and SSIs for low risk surgeries is not yet determined. Lack of a universal classification system for SSIs reduces the capacity for healthcare facilities and studies to compare outcome data. Development of international taxonomies would reduce ambiguity with both SSIs and obesity.

5.12 Summary

The complex nature of postoperative infections and individual variability make a risk calculation for any individual person very difficult, especially in the presence of multiple comorbidities (Schuster, Rechtine, Norvell, & Dettori, 2010). Although obesity appears associated with increased SSI rates in general, further studies that use standard definitions for both SSIs and obesity for individual patients undergoing low risk surgical procedures are required (Schuster et al., 2010).

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Appendix A - Data Extraction Template

Document Number	
Title	
Date of publication	
Length of time from study beginning to publication	
Purpose: Background and rationale for research	
Goals/Aims: Objectives including hypotheses	
Study type (Cohort, case control, case series)	
Study design (prospective, retrospective)	
Setting	Dates studied
	Period of recruitment and how
	Location (where and how selected) e.g. hospital vs ASC
Eligibility criteria and sources and methods of selection	Inclusion
	Exclusion
	Follow up (How - process, length of time [average and spread])
	Sample size
	How arrived at/power analysis
For matched studies, give matching criteria (number of exposed and unexposed or N/A)	
Data sources	Procedure type/ exposure (general)
	Description of procedure
	Predictors
	Confounders
Measurement and Definitions	Definition of obesity (category boundaries) and how measurement obtained
	Definition of infection and how evaluated/ obtained
	Were prophylactic Abx used (y/n)
	Description of dosing
Bias	Limitations
	Directions
	Magnitude
Statistical Methods	How was data collected (general)
	subgroups and interactions
	How addressed missing data
	How loss to follow-up was addressed
	How controlled for confounding
	Sensitivity analyses
Participant Demographics	Age (range and average)
	Sex (#)
	Differences in groups
	How missing data accounted for
Results	Unadjusted and adjusted rates, relative risk, odds ratios, etc
Other analyses	
Overall interpretation	
Generalizability	

Appendix B - Quality Assessment Matrix for Cohort and Case Controlled Studies

Quality Assessment of Cohort Studies (Articles 1-3)

Paper	Alvi et. al. 2015		Amin, Patton et. al. 2006		Ballal et.al. 2013	
Criteria	**R1**	**R1**	**R2**	**R2**	**R1**	**R2**
1. Was the research question or objective in this paper clearly stated?	Y	Y	Y	Y	Y	Y
2. Was the study population clearly specified and defined?	Y	N - Just age, gender, unilateral or bilateral and diagnosis only	N - Just age, gender, unilateral or bilateral and diagnosis only	N	Y	Y
3. Was the participation rate of eligible persons at least 50%?	Y	Y	Y	Y	Y	Y - N=92 patients
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?	Y	Y	Y	Y - N=370 knees in 320 patients	Y	Y
5. Was a sample size justification, power description, or variance and effect estimates provided?	NR	Y - Fisher's exact test only, gives rates. "M[orbid]O[besity] too small for further statistical analysis.	Y - Fisher's exact test only, gives rates. "M[orbid]O[besity] too small for further statistical analysis.	N	NR	N
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	Y	Y	Y	Y	Y	Y
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	N	N - First follow up at 6 months – No information about infection data.	N - First follow-up at 6 months – No information about infection data.	Y - 60 months (5yrs)	Y - Follow-up methodology not described	Y - 2 years follow-up
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	NA	NA	Y - grouped by different BMI, sex and weight groups	NA	Y
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	N - Variety of hospitals and surgeons not adj. for	Y	Y	Y	Y	Y
10. Was the exposure(s) assessed more than once over time?	NR	NR	NR	N	NR	N

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 1-3) con't

Paper	Alvi et. al. 2015		Amin, Patton et. al. 2006		Ballal et.al. 2013	
Criteria	**R1**	**R1**	**R2**	**R2**	**R1**	**R2**
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	NR	N - Consistent but definition for SSI is not standard	N - Consistent but definition for SSI is not standard	N	N – SSI definition was not explained, not defined	N
12. Were the outcome assessors blinded to the exposure status of participants?	NR	N	N	N	NR	N
13. Was loss to follow-up after baseline 20% or less?	NR but likely	Y	Y	Y - 5.6% loss to follow-up	Y - No loss as follow-up part of inclusion criteria	Y
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	Good matching to reduce confounders	N - Large differences between morbidly obese(m.o.) and non-obese demographics, not adjusted for	N - Large differences between morbidly obese(m.o.) and non-obese demographics, not adjusted for	N	N - Did not do statistical analysis of infections	N
Quality Rating (Good, Fair, Poor)	**Fair**	**Fair**	**Poor**	**Poor**	**Fair**	**Fair**
Rationale for quality rating	Didn't do a full follow-up (infections often occur after 30 days)	9/14 yeses – huge sample, well controlled stats, short follow-up	Little information available on demographics, nothing on co-morbidities, no confounders adjusted for	8/14 yeses, good follow-up, moderate sample size	Infections not defined and did not do statistical analysis of infections	9/14 yeses, but major problem with selection bias

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 4-6)

Paper	Chen, et.al. 2009		Chesney, et.al. 2008		Coon, et.al. 2009	
Criteria	**R1**	**R1**	**R2**	**R2**	**R1**	**R2**
1. Was the research question or objective in this paper clearly stated?	Y	Y	Y	Y	Y - Odd objective	Y
2. Was the study population clearly specified and defined?	Y - But difference in demographics between groups not reviewed for statistical significance	Y	Y - Gender, age, BMI, history	Y	Y - Gender, age, comorbidities	Y - Pts who lost more than 50lbs
3. Was the participation rate of eligible persons at least 50%?	Y	Y - N= 195 patients of 244 =79.9%	Y	Y	Y	Y
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?			Y	Y	Y	Y – n=449: 2 cohorts: 1 procedure or >1 procedure
5. Was a sample size justification, power description, or variance and effect estimates provided?	N	N	N	N	N - Selection by dates only	N
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	Y	Y	Y	Y	Y	Y
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	Y - Follow-up methodology not described	Y - minimum 1 year follow-up	Y - Follow-up methodology not described	N - Table 1 is not explained. Not clear why some procedures need 6 month follow-up and other 5yrs.	NR - Follow-up methodology not described	N Agree
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	N	NA	Y - 4 different obesity classifications (Table 4)	NA	Y - grouped BMI by different cohorts and different procedures
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	NR – diabetes but did not define whether well controlled		N - Multiple surgeons not adjusted for, surgery not described	N	N - Multiple procedures, no discussion about surgeon variability, rates by procedure not reported	N
10. Was the exposure(s) assessed more than once over time?	NR	N	NR	N	NR	N
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Y - CDC	Y	Y - Modification of CDC	Y	NR	Y - table 4 has the complications

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 4-6) con't

Paper	Chen, et.al. 2009		Chesney, et.al. 2008		Coon, et.al. 2009	
Criteria	**R1**		**R2**		**R1**	
12. Were the outcome assessors blinded to the exposure status of participants?	N	N	N	N	NR	N
13. Was loss to follow-up after baseline 20% or less?	Y – inclusion criteria included a minimum of one year follow-up	Y	Y - About 10%	Y	NR	Y
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	Y - Multivariate adj BMI confounder versus risk factor or outcome Cefazolin Abx not described	Y	Y - Abx given to all – can't compare to non-Abx results Nothing found statistically significant using x^2	Y	N Didn't adj for surgery type, age. Complications only, no matching	N
Quality Rating (Good, Fair, Poor)	**Fair**	**Fair**	**Good**	**Fair+**	**Poor**	**Poor**
Rationale for quality rating	BMI/obesity used as confounder versus outcome – demographics not adj for	8/14 yeses concur with R1		9/14 yeses. Not very advanced statistical anlaysis – no controlling for confounders (may be Fair d/t stats & other weak methods)	Selection bias not clear, possible measurement bias as weight loss self-reported, confounders not reported or accounted for, length of time for follow-up not reported so don't know if meets 30/90 days or even 1 year	8/14, but follow-up very poorly described

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 7-9 criteria)

Paper	Gould, et. al. 2006		Malinzak, et.al. 2009		Mehta, et.al. 2013	
Criteria	**R1**	**R1**	**R2**	**R2**	**R1**	**R2**
1. Was the research question or objective in this paper clearly stated?	Y - Purpose statement in abstract only	N - No direct purpose statement	Y	Y	Y - Unique determinants of obesity	Y
2. Was the study population clearly specified and defined?	Y - Age, gender only	N	N - Age, diabetes, unilateral or bilateral and dx only	N	N - Gender, BMI, obese, and diabetes only	N
3. Was the participation rate of eligible persons at least 50%?	Y	NR	Y	Y - 64%	Y	Y - 298/456 = 65.3%
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?	Y	Y	Y	Y - n=5719 knees	Y - 15 excluded as no height/weight but should have added into obesity as sub-analysis to determine if they may have changed outcome	Y - Controls were still Class III obese so all information would need to be merged for comparison to other papers
5. Was a sample size justification, power description, or variance and effect estimates provided?	N	N	N - Selection by dates only	N	N - Based on dates	N
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	Y	Y	Y	Y	Y	Y
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	Y	Y	Y - 2 years – Follow-up methodology not described	Y	Y - Follow-up methodology not described	Y
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	Y - Yes, 2 different obesity classifications	NA	Y - grouped by different BMI	NA	
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Y- Variations described but not adjusted for	Y	N - Did not report variables	N	Y	Y
10. Was the exposure(s) assessed more than once over time?		N	NR	N	NR	N
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	N - definition of wound infection – not described	N	NR	N	Y - CDC	Y

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 7-9) con't

Paper	Gould, et. al. 2006		Malinzak, et.al. 2009		Mehta, et.al. 2013	
Criteria	R1	R2	**R1**	**R2**	**R1**	**R2**
12. Were the outcome assessors blinded to the exposure status of participants?	N	N	NR	N	N	N
13. Was loss to follow-up after baseline 20% or less?	NA	NR	N - About 25%	Y	NA	Y
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	N	N	Y	N - Did not adjust for confounders	N - Rate comparisons only, no matching, multivariate adj for BMI, obesity ≥30 On to say obesity ≥30 had 12.6% incidence and MO ≥40 9% incidence but stat sig not carried out	N
Quality Rating (Good, Fair, Poor)	**Fair**	**Poor**	**Good**	**Fair**	**Fair**	**Fair**
Rationale for quality rating	Super-super obese compared to super-obese – unless obese compared in some way to non-obese, not helpful	5/14 yeses, methods very vague in this study	Infection definition not standard so not comparable, not all patients included in study (483 without a BMI left out), 25% lost to follow-up – could influence the outcome, especially if all fell within same category – Odds ratio not rates	7/14 yeses, very vague stats description, not controlled for confounders	Unique predictors – body fat distribution, depth of lamina, thickness of lumbar level subcu. fat	8/14, not controlled for confounders

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 10-12)

Paper	Namba et.al. 2005		Namdari, et.al. 2010		Nemerofsky, et.al. 2006	
Criteria	**R1**	**R1**	**R2**	**R2**	**R1**	**R2**
1. Was the research question or objective in this paper clearly stated?	Y	Y	Y	Y	Y	Y
2. Was the study population clearly specified and defined?	Y	Y	N - Very little reported, multiple linear regression (good), not matched, med/surg/ demographics potential confounders, diabetes (more prevalent in obesity, but not adj) – outcomes were rates only	N - Not clearly stated that cases were obese and controls were non-obese	Y - Gender, age, smokers, non-smoker, comorbidities	Y
3. Was the participation rate of eligible persons at least 50%?	Y	Y - N=1813 patients	Y	Y	Y	Y
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?	Y	Y	Y - Excluded cases if no function score but this could have lost cases of infection	Y	Y	Y
5. Was a sample size justification, power description, or variance and effect estimates provided?	NR	N	Y - But justified based on continuous variable DASH, not infection	Y - 57 infected 97 not infected N=154 Nearly 2:1 match	N	N
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	Y	Y	Y	Y	Y	Y
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	Y - 1 year follow-up	Y	Y – Follow-up methodology not described	Y – Follow-up methodology not described	Y	N - Average follow-up only 8 months
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	N	NA	NA	NA	Y - 3 different obesity classifications
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Y	Y	Y - Different techniques accounted for	Y	Y - BMI definitions not standard	Y
10. Was the exposure(s) assessed more than once over time?	NR	N	NR	NR	NR	N
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Y - Not CDC definitions so hard to use as comparator	Y	N	N	N - definition of wound infection – not described	N

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 10-12) con't

Paper	Namba et.al. 2005		Namdari, et.al. 2010		Nemerofsky, et.al. 2006	
Criteria	**R1**	**R2**	**R1**	**R2**	**R1**	**R2**
12. Were the outcome assessors blinded to the exposure status of participants?	NR	N	N	N	N	N
13. Was loss to follow-up after baseline 20% or less?	Y	Y - 0 lost to follow-up	NR	NR	Y	Y
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	N - Multiple surgeons, multiple hospitals, Abx differences – didn't match. Although significant results, didn't report adjusted rates on ASA status (co-morbidities).	N	N	N	N - Comorbidities not controlled for, odds ratios not presented	N
Quality Rating (Good, Fair, Poor)	**Fair**	**Fair**	**Good**	**Fair +**	**Poor**	**Poor**
Rationale for quality rating	Lengths of admissions post surgery were greater than 24 hours so results do not reflect low risk surgeries	9/14, but did report advanced statistics	Rates only, no stats on relationship between obesity and SSI, nay have been loss of infection cases due to exclusion factors	6/12 yeses but better stats than most so I'm ok with "Good but"	SSI definitions not described, comorbidities not controlled for, obesity definitions not standard	8/14 yeses, but very poorly written study

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Article 13 - 15)

Paper	Oliak, et.al. 2002		Suzuki, et.al. 2011		Wallace, et.al. 2014	
Criteria	**R1**	**R1**	**R2**	**R2**	**R1**	**R2**
1. Was the research question or objective in this paper clearly stated?	Y	Y	Y	Y - Not traditional way of stating study goal, but clear	Y	Yes
2. Was the study population clearly specified and defined?	Y - Gender, age, comorbidities only	Y	Y - Age, gender, BMI, comorbidities, smoking, steroids, previous OR same site	Y	Y- primary knee surgery,	Yes, data from 1995-2011
3. Was the participation rate of eligible persons at least 50%?	Y	Y	Y	Y - N=1146 +180 (missing data)=86%	Y – 66%	Yes, 66% had complete data
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?	Y - Both groups would be considered Class III obese – would have to merge to compare	Y	Y - Deep infections only – did not provided definitions	Y	Y – consecutive database	Yes,
5. Was a sample size justification, power description, or variance and effect estimates provided?	N	N	N	N	N- based on dates	No
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	Y	Y	Y	Y	Y	Yes, BMIs were based on data closest prior to surgery
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	NR - Follow-up methodology not described	N	Y - Follow up methodology not described	Y	N – timeframe was less than 1 year which may underestimate the number of wound infections	Yes, within 6 months
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	Y	NA	N	Y	Yes, BMIs classified based on WHO
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Y - Variations described but not adjusted for	Y	N - Multiple surgeons not adjusted for, surgery not described	N	Y- logistic regression and adjustment for potential confounders robust	Yes, the authors point to a study that demonstrated validation of diagnoses in the Clinical Practice Research Datalink (CPRD) database

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Cohort Studies (Articles 13-15) con't

Paper	Oliak, et.al. 2002		Suzuki, et.al. 2011		Wallace, et.al. 2014	
Criteria	**R1**	**R2**	**R1**	**R2**	**R1**	**R2**
10. Was the exposure(s) assessed more than once over time?	NR	N	NR	N	N	No
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	N - definition of wound infection – not described	N	N - Definition for early and late not standard – used throughout	N	NR	Yes, based on ICD-10
12. Were the outcome assessors blinded to the exposure status of participants?	N	N	N	N	N	NR
13. Was loss to follow-up after baseline 20% or less?	NR	N	Y – about 8%	Y	NA – exclusion criteria included patients that did not remain under care for length of review	NR
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	Y – Adjusted comorbidites and differences in demographics as well as outcomes – none statistically significant	N	Y	Y	Y – robust review	Yes
Quality Rating (Good, Fair, Poor)	**Good**	**Fair**	**Good**	**Good**	**Good**	**Good**
Rationale for quality rating	Can't be used in SR as both groups are Class III obese	7/14 yeses, not very rigorous analysis	Deep infections only Analysis of confounders well done	8/14 yeses. Clearly written, but missing good definitions	Sample size huge, robust analysis of confounders. Clear aim statement and analysis well described and applicable	9/14 Controlled for many possibly confounding variables. Data source appears valid and reliable. Sample size very large.

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Case-Control Studies (Articles 1-2)

Paper	Amin, Clayton et.al. 2006		Foran, et. al. 2004	
Criteria	**R1**	**R2**	**R1**	**R2**
1. Was the research question or objective in this paper clearly stated and appropriate?	Y	Y	**R1**	**R2**
2. Was the study population clearly specified and defined?	Y	Y	Y	Y
3. Did the authors include a sample size justification?	N – very small sample size	N - 38 obese, 38 non obese N =76 1:1 match	N	N - 68 obese patients+ 68 non-obese patients N=136 1:1 match
4. Were controls selected or recruited from the same or similar population that gave rise to the cases (including the same timeframe)?	Y	Y	Y	Y
5. Were the definitions, inclusion and exclusion criteria, algorithms or processes used to identify or select cases and controls valid, reliable, and implemented consistently across all study participants?	Y	Y	Y	Y
6. Were the cases clearly defined and differentiated from controls?	Y	Y - Matched based on infected or not infected	Y	Y - Matched based on obese or not obese
7. If less than 100 percent of eligible cases and/or controls were selected for the study, were the cases and/or controls randomly selected from those eligible?	N	N	NA	Y
8. Was there use of concurrent controls?	NR	N - Controls not enrolled on same day	NR	N - Controls not enrolled on same day
9. Were the investigators able to confirm that the exposure/risk occurred prior to the development of the condition or event that defined a participant as a case?	Y - But non-morbidly obese were normal or overweight, hard to compare to other outcomes	Y	Y	NR
10. Were the measures of exposure/risk clearly defined, valid, reliable, and implemented consistently (including the same time period) across all study participants?	N	N	N - Review at 30 days, not 90 - 1 year follow-up not reported	Y - Followed for 5 years
11. Were the assessors of exposure/risk blinded to the case or control status of participants?	Y - The only study with blinding reported	Y	NR	Y - Blinded to outcome at time of matching
12. Were key potential confounding variables measured and adjusted statistically in the analyses? If matching was used, did the investigators account for matching during study analysis?	N - Not adj for surgeon experience Matched for age, gender, diagnosis, type of of prosthesis, KSS	N - Change of surgical procedure with some of subjects	Y - Good matching to reduce confounders	Same device used on all patients.
Quality Rating (Good, Fair, Poor)	**Fair**	**Fair**	**Fair**	**Fair**

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Quality Assessment of Case-Control Studies (Articles 3-4)

Paper	Koutsoumbelis, et. al. 2011		Winiarsky et.al., 1998	
Criteria	**R1**	**R2**	**R1**	**R2**
1. Was the research question or objective in this paper clearly stated and appropriate?	Y	Y - Very clear	Y	Y
2. Was the study population clearly specified and defined?	Y	Y - Retrospective	Y	Y
3. Did the authors include a sample size justification?	N	N - 84 infected patients & 168 not infected N=252 2:1 match -- good	Y	Y
4. Were controls selected or recruited from the same or similar population that gave rise to the cases (including the same timeframe)?	Y	Y	N - Selection by dates	N - 40 obese patients, 1539 non-obese patients (over-matched) N=1579 39:1 match –
5. Were the definitions, inclusion and exclusion criteria, algorithms or processes used to identify or select cases and controls valid, reliable, and implemented consistently across all study participants?	Y	Y	Y - 40 pt/50 knees in 14 years	Y - Total 1768 knees+50 knees, only 40 pts obese
6. Were the cases clearly defined and differentiated from controls?	Y	Y - Randomly selected from non-infected w/same time/procedure	Y	Y
7. If less than 100 percent of eligible cases and/or controls were selected for the study, were the cases and/or controls randomly selected from those eligible?	Y	Y - Randomly selected from non-infected w/same time/procedure	Y	Y - Matched based on obese or not obese
8. Was there use of concurrent controls?	Y	N - Controls not enrolled on same day	NA	Y - Selected to match but if more than 1 didn't identify random selection
9. Were the investigators able to confirm that the exposure/risk occurred prior to the development of the condition or event that defined a participant as a case?	Y - Excluded anyone with chance of prior infection	Y	NR	N - Controls not enrolled on same day
10. Were the measures of exposure/risk clearly defined, valid, reliable, and implemented consistently (including the same time period) across all study participants?	Y	Y	Y	Y
11. Were the assessors of exposure/risk blinded to the case or control status of participants?	N	NR	N - Drain usage and prostheses not consistent	N
12. Were key potential confounding variables measured and adjusted statistically in the analyses? If matching was used, did the investigators account for matching during study analysis?	Y - ABx dose rate dependent on weight (1 or 2 g Cefazolin) and ongoing for 24 hours, matched with 2 randomly selected	Y	N	N
Quality Rating (Good, Fair, Poor)	**Good**	**Good**	**Fair**	**Fair**
Rationale for quality rating		9/12 yeses and good stats methods. Very good paper, but some of the data were retrospective, so may have missed some cases.		

Y=Yes Present; N=Not Present; CD=cannot determine; NA=not applicable; NR=not reported

Appendix C - US-CDC Definitions of Surgical Site Infections (1988, 1992, and 2016)

	Definitions by Year		
Term	**1988***	**1992****	**2016*****
Operative procedure definition			Operative procedure is a procedure that: takes place during an operation where at least one incision (including laparoscopic approach) is made through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure AND takes place in an operating room (OR), defined as a patient care area that met the Facilities Guidelines Institute's (FGI) or American Institute of Architects' (AIA) criteria for an operating room when it was constructed or renovated Exclusion ASA score of VI
Superficial Incisional	"Incisional surgical wound" Infection occurs at incision site within 30 days after surgery AND involves skin, subcutaneous tissue, or muscle above the fascial layer AND any of: • Purulent drainage from incision or drain located above fascial layer • Organism isolated from culture of fluid from closed wound • Surgeon deliberately opens wound • Surgeon or attending diagnosis of infection	Infection occurs within 30 days after procedure and involves only skin or subcutaneous tissue of the incision. AND at least one of the following: • Purulent drainage from the incision • Organisms isolated from an aseptic specimen, culture of fluid or tissue PLUS one of: • Pain or tenderness • Localized swelling • Redness or heat OR Diagnosis of superficial SSI by the surgeon or attending physician	Infection occurs within 30 days after procedure and involves only skin or subcutaneous tissue of the incision AND at least one of the following: • Purulent drainage from the incision • Organisms identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment • Superficial incision that is deliberately opened by a surgeon, attending physician** or other designee and culture or non-culture based testing is not performed PLUS one of: ○ Pain or tenderness ○ Localized swelling ○ Redness or heat • Diagnosis of superficial SSI by the surgeon or attending physician

Note. Appendix C adapted from:
* CDC Definitions for Nosocomial Infections by J. Garner, W. Jarvis, T.G. Emori, T. Horan & J. Hughes, *AJIC16(3),* Copyright 1988 by the American Journal of Infection Control
** Consensus Paper on the Surveillance of Surgical Wound Infections by The Society for Hospital Epidemiology of America, Association for Practitioners in Infection Control, retrieved from http://www.jstor.org.ezproxy.library.ubc.ca/stable/30148463 Copyright 1992 by US-CDC
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Appendix C US-CDC Definitions of Surgical Site Infections for years 1988, 1992, and 2016 (con't)

	Definitions by Year		
Term	**1988***	**1992****	**2016*****
Deep Incisional	"Deep surgical wound" Infection occurs at operative site within 30 days after surgery if no implant is left in place or within 1 year if implant AND infection appears related to surgery AND infection involves tissues or spaces at or beneath fascial layer AND any of: • Purulent drainage from drain placed below fascial layer • Wound spontaneously dehisces or is deliberately opened when patient has fever (<38 C) and or localized pain or tenderness • An abscess or other evidence of infection seen on direct examination during surgery or by histopathologic exam • Surgeon's diagnosis	Infection occurs within 30 days after procedure if no implant or within one year if an implant is in place and the infection appears to be related to the procedure and involves deep soft tissues (fascial and muscle layers) AND at least one of the following: • purulent drainage from the deep incision (fascial and muscle layers) • spontaneously dehisces or is deliberately opened by a surgeon PLUS any one of: ○ Fever (>38) ○ Localized pain or tenderness ○ Abscess OR Diagnosis of deep SSI by the surgeon or attending physician	Infection occurs within 30 or 90 days[Δ] after the NHSN operative procedure according to the list presented by the CDC involves deep soft tissues (fascial and muscle layers) AND at least one of the following: • purulent drainage from the deep incision (fascial and muscle layers) • spontaneously dehisces or is deliberately opened by a surgeon, , attending physician** or other designee and organism is identified by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment OR culture or non-culture based microbiologic testing method is not performed AND patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or tenderness • an abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test

[Δ]The only procedures found in ASCs that meet the 90-day surveillance requirement for SSI are breast surgery, lumbar spinal fusion, and knee prostheses (TKA). All other procedures require 30 day surveillance

Note. Appendix C adapted from:

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Appendix C US-CDC Definitions of Surgical Site Infections for years 1988, 1992, and 2016 (con't)

	Definitions by Year		
Term	**1988***	**1992****	**2016*****
Organ space	No definition provided	Infection occurs within 30 days after procedure if no implant or within one year if an implant is in place and the infection appears to be related to the procedure and the infection involves and organ or spaces (other than the incision) manipulated during the procedure AND at least one of • Purulent drainage from a drain through a stab wound • Organism isolated • Abscess or evidence on direct examination, reoperation or histopathologic or radiologic exam OR Diagnosis of organ space SSI by the surgeon or attending physician	Infection occurs within 30 or 90 days after the NHSN operative procedure according to the list presented by the CDC AND infection involves any part of the body deeper than the fascial/muscle layers, that is opened or manipulated during the operative procedure AND patient has at least one of the following: • purulent drainage from a drain that is placed into the organ/space (e.g., closed suction drainage system, open drain, T-tube drain, CT guided drainage) • organisms are identified from an aseptically-obtained fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment. • an abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test AND meets at least one criterion for a specific organ/space infection site listed in CDC Table∞

∞Organ space SSIs that are associated with ASC procedures would be bone (osteomyelitis), breast (abscess or mastitis), lumbar spine (disc space, spinal abscess), eye (any infection other than conjunctivitis), bariatric surgery (intraabdominal), TKA (joint infection or periprosthetic infection), oral cavity (any infection of the mouth, tongue or gums), skin infection, soft tissue infection.

Note. Appendix C adapted from:
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