PHYSICIANS' ASSISTANTS' INFLUENCE ON SURGICAL HARVEST INFECTION FOLLOWING CARDIAC CORONARY SURGERY IN SAUDI: RETROSPECTIVE COHORT PILOT STUDY

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Abstract- Surgical operators play a critical role in minimizing the incidence of surgical wound complications (SWCs) at the harvest site in coronary artery surgery; however, in Saudi Arabia, non-medical practitioners (physicians' assistants) have been introduced to offset the shortage of physicians in cardiac surgery. Different levels of education and training are documented to influence the occurrence of SWCs at harvest sites; however, little attention has been paid in the literature to the influence of surgical operators on the incidence of harvest site SWCs.

Index Terms— CABG, Cardiac patients, Harvest, Physician's assistants', Post operative complications, Surgical site.

1 INTRODUCTION

Coronary artery disease (CAD) is a global health issue that contributes to disability and death (Aljefree and Ahmed 2015). CAD is caused by a blockage of the coronary arteries, which restricts the flow of blood to the heart (Gelb and Chung 2014). Patients with CAD usually suffer from symptoms such as chest pain or discomfort and shortage of breath (Skelly et al. 2016). In practice, there are several options to treat symptoms of CAD; these options include lifestyle interventions, pharmacological interventions and invasive medical interventions such as percutaneous coronary intervention (PCI) (Cao et al. 2013). However, in certain complex conditions, these treatment options are not sufficient; in such cases, a surgical intervention such as coronary artery bypass grafts (CABG) is indicated (Cao et al. 2013).

Diodato and Chedrawy (2014) defined CABG as an open heart surgical procedure in which a section of blood vessel conduit is anastomosed to the targeted coronary artery from the aorta in order to bypass the blocked part of the coronary artery, improving the supply of the blood to the myocardium. To perform CABG, it is necessary to extract a conduit from the patient's circulatory system in order to achieve the goal of the surgery (Diodato and Chedrawy 2014). The most commonly used conduits in CABG are the left and right mammary arteries from the internal chest walls, the radial artery from the arm, and the left and right long saphenous veins from the legs (Cao et al. 2013).

Surgical wound complications (SWCs) post CABG surgery has a substantial impact on both healthcare systems and patients (Cove et al. 2012; Bryan et al. 2013). Iyer et al. (2011) suggested that the SWCs cause increases in morbidity and mortality rates, and in the costs of cardiac surgery settings. Due to the nature of CABG, SWCs can occur at two sites: the graft harvest site and/or the sternal wound (Bryan et al. 2013). Research by Berg et al. (2011) reported SWC rates of 5.1% and 8.9% for sternal and harvest locations respectively. In some cases, SWCs post conduit harvests require additional surgical intervention such as debridement, with possible lower extremity revascularization or loss of the limb in the worst case scenario (Turtiainen and Hakala 2013). Thus, the issue of graft SWCs following coronary artery bypass is of genuine scientific and clinical interest.

The most common forms of SWCs post conduit harvest are seroma (a collection of serous fluid in the dead space of the surgical wound), hematoma (a blood collection outside of vessels), infection (either superficial infection involving only the skin or subcutaneous tissues or deep infection involving the fascia or muscle layers) and wound dehiscence (an unintended, partial or full thickness breakdown of a surgical wound) (Sørensen et al. 2005; Sharma et al. 2009; East et al. 2013).

The increasing need for the procedures of CABG in the kingdom of Saudi Arabia has not been matched with an increase in the number of physicians (Alreshidan et al. 2014; Grover et al. 2009). This shortfall of physicians has subsequently led to the physician's assistants' introduction in cardiac surgery filed (Polansky 2007). Within CABG procedures, the role of physicians' assistants, when utilized, is to harvest and prepare the graft prior to implantation (Thourani and Miller 2006). The harvesting of the conduit is also carried out by medically qualified staff, but often these practitioners are junior team members (Polansky 2007).

Different levels of operators' education and training can affect the outcomes of SWCs post-harvesting; this may relate to the variation in the level of surgical skills (Moulton et al. 2006; Pear and Theresa 2009). Killian et al. (2001) suggest that there is an association between the occurrence of SWCs post-operatively and operators' surgical skills. In this context, the role of the physician's assistant becomes a potential influencing factor for SWCs at the harvest site in CABG. A preliminary review of the literature revealed a lack of studies that investigated the effect of the level of operators' surgical skills on the frequency of SWCs at the harvest site in CABG. Thus, this study sets out to explore the association of surgical operators with the occurrence of SWCs after graft harvesting. Investigating this association could enhance patient safety by adopting new strategies that can minimize the occurrence of SWCs at the harvest site (Aggarwal et al. 2010). While the skill level of operators, such as physicians' assistants and surgeons in training, is very likely to influence surgical outcomes at the harvest site, it is only one among many other potential factors, as noted by East et al. (2013) and Turtiainen and Hakala (2013). Therefore, the next chapter of this work will explore the literature in more depth to identify and investigate the influences on surgical site/wound complications post-CABG.

2. Literature Review

Literature reviews serve to enable researchers and practitioners to examine their field of interest (Houser 2015). Parahoo (2014) suggested the use of a literature review approach to specify the current situation and identify gaps in the knowledge surrounding the studied problem. Thus, this chapter aims to explore and examine existing evidence around influences on surgical harvest site complications following CABG to build an argument to support the need for the current research.

2.1 Search Strategy

In order to conduct a comprehensive search, two activities were utilized to conduct a search on the topic of "influences on surgical harvest site complications following CABG". These activities are electronic databases and back-chaining method where collecting more evidence from the identified articles reference's lists; these activities will help to gather more relative evidence (Rees 2011; LoBiondo-Wood and Haber 2014).

The author conducted an initial search using Google Scholar to scope the topic only (Neal 2009). Further in-depth searching was carried out using PubMed, Scopus and Medline via Ovid. These databases were chosen because they are the most common web sources used at a global level by healthcare practitioners (Greenhalgh 2014). They were accessed through Cardiff University electronic resources. All databases were limited to full text and human studies published in English, which is the most commonly used language for scientific publication (Lobachev 2008). As the initial scope of the literature indicated that limited relevant evidence was available, no time restrictions were considered, so as to maximize potential material for inclusion (Houser 2015).

The medical subject heading terms "conduit harvest", "influences", "complications", "coronary artery bypass graft ", "smoking", operative technique", "infection", "surgeon volume", "surgical skills", "harvest site", "comorbidity factors", "Saudi", "hair removal", "endoscopic", "prophylactic", "antibiotics", "duration", "intraaortic balloon machine" and "invasive" were used in different combinations using the Boolean operators "AND" and "OR". Synonyms of these search terms were also used to ensure a broader perspective on all the available relevant studies (Houser 2015). The following table contains a summary of initial hits for each database:

Table 2.1: Summary of initial hits for the used databases

Database	Initial hits	Abstract read	Full text read	Included articles
PubMed	519	56	30	14
Scopus	203	33	19	12

Medline via Ovid	132	20	7	0

(For more detailed search information, see appendices 2.A).

2.2 Selection Criteria

Clear statements of the inclusion criteria while reviewing the literature will help to gather relevant evidence in optimal time (Houser 2015). The criteria for studies included for this review were: all primary studies that were conducted to investigate risk factors of SWCs post conduit harvesting alone or with sternal involvement. If any influencing factors were not discussed sufficiently within identified studies, additional studies were included for more illustration of these factors. Studies should be published in peer-reviewed journals; this will contribute to the body of knowledge which forms the evidence upon which best practice is based (Magarey et al. 2007).

However, as there were numerous primary studies with different designs that examined the same risk factor, the author elected to use only the best designs according to the evidence pyramid in order to establish the best way to form meaningful arguments from the literature (Burns et al. 2011). The assessment of potentially eligible articles was based on a title review, followed by an abstract review. When reviewing an article's abstract suggested potential eligibility, the article was read in full text and final decision on inclusion/exclusion was made.

2.3 Themes arising from the literature

Risk factors that influence the incidence of SWCs at the harvesting site are classified into two main categories: endogenous and exogenous factors (Turtiainen and Hakala 2013). Endogenous factors are defined as those factors that are related to patients, such as preoperative factors. These include demographic factors such as age and gender; and comorbidity factors such as the presence of diabetes, peripheral vascular disease, obesity and tobacco smoking (Turtiainen and Hakala 2013). Exogenous factors include all factors that are related to the process and procedures. These include perioperative factors such as the use of an intra-aortic balloon pump and the duration of prophylactic antibiotics; and intra-operative factors such as the harvesting and wound closing method (Pear 2007). To facilitate the interpretation of the gathered evidence, it will be discussed according to the categories of investigated risk factors documented above.

2.3.1 Endogenous Factors

2.3.1.1 Demographic Factors

Female gender is well documented to be a main risk factor for SWCs at harvesting site post CABG. Vuorisalo et al. (1998) conducted a retrospective study to investigate preoperative and perioperative features that might lead to surgical wound complication in 884 patients who had undergone CABG. They concluded that female gender was an independent predictor for harvest site complications (P=.003). In addition, Carpino et al. (2000) found similar results to Vuorisalo et al. (1998) after conducting a prospective randomized trial to investigate the effectiveness of harvesting methods (open versus endoscopic). They found that female gender was an independent predictor for complications at the harvest site (P =.04). Moreover, in 2000, Paletta et al. reviewed 3,525 patients who underwent CABG over ten years in one institution to investigate the complications post conduit harvest. They found a significant association between female gender and SWCs at the harvest site (P= 0.0007).

Additionally, in a Swedish study from 2004, Swenne et al. carried out a prospective study to register the incidence of SWCs post CABG at two locations – the donor harvest site and the sternal site – and to investigate potential risk factors for the development of SWCs. Swenne et al. (2004) recruited 374 patients without providing any justification for recruiting this particular number; this study revealed a strong association between female gender and SWCs at the harvesting site (P< 0.001). Similarly, Kayacioglu et al. (2007) in Turkey conducted a prospective cohort study to determine the predictors of SWCs at the harvesting site among 120 patients and also found the female gender to be an independent predictor (P= 0.017).

In 2008, Abbaszadeh et al. carried out a retrospective study in Iran to review 4029 patients who had undergone CABG between August 1997 and August 2003 at their centre, aiming to explore the prevalence and examine relevant risk factors for SWCs at the harvest site and the sternum. After reviewing patients' charts, Abbaszadeh et al. (2008) identified many risk factors: female gender was again one of those factors that influenced SWCs at the harvest site (P < 0.002). Finally, Gaballah and Abo Elnor (2013), in Egypt, found a highly significant association between female gender and SWCs at the harvest site (P= 0.01); this was revealed after they had retrospectively reviewed the notes of one hundred patients who had undergone CABG at their centre between September 2009 and December 2010.

Thomas et al. (1999), in a retrospective evaluation, identified patient age (67.9 years; p = 0.007) and female gender (*P*, 0.001) as independent factors for the development of SWCs at the harvesting site. These findings were supported by the results of Olsen et al. (2003), who also found female gender and older age (>75 years) to be independent variables in the development of SWCs (p=0.014 and p=0.013, respectively). This inference resulted from a retrospective case control study conducted by Olsen et al. (2003) in the US to investigate the causative factors of harvest site infections following CABG. Using the Society of Thoracic Surgeons database, Olsen et al. (2003) collected data from 1980 patients who had undergone CABG surgery between January 1, 1996 and June 30, 1999. Similarly, Sharma et al. (2009) retrospectively reviewed the records of 3578 patients who had undergone CABG between January 2000 and September 2004 to evaluate predisposing factors to

SWCs at the harvesting site: increased age (>65 years; P= 0.03) and female gender (P= .008) were among the predisposing factors that were detected in this study.

All of the above-mentioned studies that reported patients' demographic characteristics as risk factors for SWCs post conduit harvest were conducted retrospectively except for the works of Carpino et al. (2000) Swenne et al. (2004), and Kayacioglu et al. (2007). Therefore, the methodological quality of most of these studies is suboptimal. The retrospective study design is considered to be a weak design due to the high possibility of selection bias (Parahoo 2014). Additionally, all of the retrospective studies have used medical records to collect their data: thus, the accuracy of the documented data is potentially questionable (Wickson-Griffiths et al. 2014).

None of these studies have justified their sample size, raising the question of the accuracy of their results due to the possibility that the results will be influenced by statistical errors (Salkind 2014). Nevertheless, number of female participants within all above discussed studies is very low. Thus, results that suggested strong associations between the female gender and the increase in patients 'age and the occurrence of SWCs at the donor site might have been influenced by a statistical error known as type I error, which arises when a true null hypothesis is rejected (Salkind 2014).

2.3.1.2 Comorbidity Factors

Diabetes mellitus and peripheral vascular disease have been shown to be independent risk factors for SWCs post conduit harvest by many studies. For example, Paletta et al. (2000) found a significant associations between diabetes (P= 0.01) and peripheral vascular disease (P<0.0001) and the occurrence of SWCs post harvesting. Furthermore, a retrospective study conducted by Thomas et al. (1999) also found a significant association (P= 0.005) between diabetes and SWCs post harvesting; peripheral vascular disease was documented as an independent predictor of SWCs but the P-value was not calculated, which prevents any meaningful identification of the claimed association (Salkind 2014).

Moreover, Spelman et al. (2000) reviewed 693 patients who underwent CABG, of whom 42 developed SWCs at the donor site. Diabetes was significantly associated with SWCs (P= 0.001). A significant association between diabetes and SWCs post harvesting (p = 0.025) was found also by Brandt et al. (2004) after reviewing 509 consecutive patients who underwent CABG. This result was also supported by the findings of studies conducted by Kayacioglu et al. (2007) and Sharma et al. (2009), revealing a strong association between diabetes and SWCs at the harvest site (P<0.031, P< 0.001 respectively). In 2005, Ku et al. in Taiwan recruited 471 patients in a prospective cohort study to investigate the rate and risk factors of SWCs post CABG; they found a highly significant association between peripheral vascular disease and the occurrence of SWCs at the harvest site (P= 0.0020). This association was consistent with Paletta et al. (2000) (*P*< 0.0001). On the other hand, comorbidity factors like chronic renal insufficiency (creatinine >2 Milligrams per Decilitre (mg/dL)) and congestive heart failure (ejection fraction < 40%) were found to be significantly correlated with the occurrence of SWCs post conduit harvesting; these correlations were only documented by Sharma et al. (2009) ($P < 0.001$and $P= .004$) for the chronic renal insufficiency and congestive heart failure respectively.

Except for Ku et al. (2005), all of the reviewed studies that reported diabetes, peripheral vascular disease, chronic renal insufficiency and congestive heart failure as significant predictors for SWCs at the harvesting site after CABG are limited by their methodological nature (retrospective design), due to the limitations previously stated. In addition, no details on sample size justification were provided in the research conducted by Ku et al. (2005): thus, their claim might be false because of the high possibility that their results are influenced by type I error, as previously explained.

Obesity is also found to be an independent risk factor for SWCs at the harvest site by a number of studies: Spelman et al. (2000) found an association of ($P = 0.001$), while the associations found by Olsen et al. (2003), Kayacioglu et al. (2007) and Sharma et al. 2009 were $P < 001$, $P = 0.045$ and $P < 0.001$, respectively. Of these studies, only Olsen et al. (2003) specified the obesity grade, which was considered to be an independent risk factor for SWCs post conduit harvesting, while Spelman et al. (2000), Kayacioglu et al. (2007) and Sharma et al. (2009) failed to determine the obesity grade.

Obese individuals are classified according to body-mass index (BMI: World Health Organization 2015). Flegal et al. (2010) define the BMI as weight in kilograms divided by the square of height in meters (kg/m^2); BMI categorizes individuals into four groups:

- Underweight (BMI <18.50 kg/m^2).
- Normal weight (18.50 - 24.99 kg/m^2).
- Overweight (≥25.00 kg/m^2).
- Obese (≥30.00 kg/m^2).

In accordance with the BMI values, obese individuals are further classified into three grades:

- Grade I (30.00 - 34.99 kg/m^2).
- Grade II (35.00 - 39.99 kg/m^2).
- Grade III (≥40.00 kg/m^2).

Given the absence of relevant information from the identified studies, the degree of obesity that is associated with SWCs post harvesting is not clear in the literature. ***2.3.1.3 Tobacco Smoking*** Cigarette smoking has been shown to cause hypovolemia and hypoxia of the tissues, leading to delays in primary wound healing and therefore causing SWCs (Hoogendoorn et al. 2002; Belda et al. 2005). Consistent with these findings, in 2016, Sharif-Kashani conducted a large prospective cohort study in Iran to investigate the association of smoking with SWCs post-CABG; they recruited 810 patients from June 2007 to August 2013, distributing them equally into two groups, namely smokers and non-smokers. This study revealed a strong association between tobacco use and SWCs post harvesting (P= 0.010). However, in observational studies, there are confounding variables that cannot be controlled by researchers, such as demographic variables and comorbidities; this will increase the challenge of estimating particular risk factors for SWCs (Korol 2013).

Similar results have also been revealed by clinical trials in other surgical specialties. For example, Møller et al. (2002) conducted a multicentre RCT in Denmark to examine the effect of preoperative smoking intervention on the occurrence of SWCs following hip and knee replacement surgeries. Møller et al. (2002) randomly distributed 120 patients into two equal groups via a valid randomization strategy using block randomization and opaque sealed envelopes: the control group included patients who received standard care and the intervention group included patients who had nicotine replacement therapy and either smoking cessation or at least a 50% reduction in smoking (Parahoo 2014). A significant reduction in SWCs was noted in the intervention group (P= 0.0003). Furthermore, in the same geographical setting, Sorensen et al. (2003) conducted an RCT to investigate the effects of abstinence from smoking on the frequency of SWCs. Without any justification, Sorensen et al. (2003) recruited 48 smokers and 30 patients who had never smoked. The smokers were subdivided and randomly allocated into two subgroups: smokers (16 patients) and abstinence from smoking (32 patients); no details were provided regarding allocation procedure. Sorensen et al. (2003) demonstrated that abstinence from smoking for as little as four weeks significantly reduces SWCs ($P < 0.05$). Although this result is consistent with the studies discussed previously, this RCT suffers from many limitations, such as an unbalanced ratio between groups, which will decrease the study power, the lack of details on randomization technique, which will increase selection bias, and the lack of a power calculation for sample size (Houser 2015).

Due to the shortfall in the relevant published studies, the determination of patient- related factors for SWCs following graft harvesting surgery could not be ascertained.

2.3.2 Exogenous factors

The exogenous factors such as duration of antibiotic prophylaxes, use of invasive devises, operative techniques and level of surgical skills are considered to be independent risk factors for the occurrence of SWCs at harvest site, separate from the existence of demographic and comorbidity factors (Sahni et al. 2016).

2.3.2.1 Antibiotic Prophylaxis Duration

Although the use of prophylactic antibiotics prior to CABG is recommended to reduce the incidence of SWCs after surgery, the optimal duration during which the antibiotics should be given remains debatable (Enzler et al. 2011; Kappeler et al. 2011).

With the aim of finding out the actual effects of different prophylactic antibiotic regimens on the occurrence of the SWCs after CABG surgery Jewell et al. (1988) in the US conducted prospectively RCT. The researchers in this RCT recruited 200 CABG patients and assigned them equally into tow prophylactic antibiotic regimens groups named: A and B. Two days prior anesthetic induction, all participants received intravenous cephalothin as prophylactic agent. Only participants in group A received additional cephalexin four times a day orally for three extra days after CABG. After following up the patients up to two months, Jewell et al. (1988) conclude that, the difference in the SWCs occurrence that exists between studied prophylactic antibiotic regimens was not significant ($P > 0.05$). However, the accuracy of this result decreased by many limitations such as unknown participants' baseline characteristics which increase the possibility of producing imbalance in baseline variables between study' groups that can bias statistical tests (Egbewale et al. 2014). This is also accompanied by the lack of the randomization strategy which taint the result as previously stated; additionally, it is unknown wither or not the recruited numbers were sufficient to detect a difference if exists due to the lack of sample size justification (Egbewale et al. 2014).

In the Netherlands, prospective randomized study carried out by Nooyen et al. (1994) to investigate the optimal prophylactic antibiotic regimens that reduce the incidence of SWCs after CABG; thus, the researchers in this RCT have compare the effects of single dose of prophylactic antibiotic as intervention group (A) with their routine practice of prophylactic antibiotic (20 mg/kg of cefuroxime intravenously three times a day for three consecutive days) as a control group (B). By using a valid randomization tool such as computer generated code as previously stated, Nooyen et al. (1994) randomly assigned 844 patients equally to studies groups: patients in group A received the routine dose of cefuroxime intravenously at the anaesthesia' induction only, while patients in group B received the routine practice previously stated. The researchers assessed the SWCs at harvest site and sternum only at day seven after surgery and not thereafter. Nooyen et al. (1994) did not detect any significant difference between studies groups in terms of SWCs either at harvest site or at sternum ($P = 0.07$). However, this result is weakening by number of limitations include the fact that this RCT was underpowered as acknowledged by the researchers. In addition, the included participants are not representing the actual CABG population as the study only was target the "uncomplicated" procedures that required less than six hours of operative time (Cao et al. 2013). Additionally, the very short follow up as SWCs is well documented to manifest more than two weeks after CABG (Sharma et al. 2009). Nevertheless, Nooyen et al. (1994) acknowledged a drug company as a fund source; this may negatively affect the credibility and integrity of the research due to the possibility of conflict of interest (Brennan et al. 2006).

As recent as 2016, Shoulders et al. in the US, investigated the effect of intraoperative continuous-infusion (CI) of prophylactic cefazolin on reducing the SWCs' incidence compared with intermittent (INT) dosing of prophylactic cefazolin in CABG patients. With a retrospective quasi-experimental cohort design, Shoulders et al. (2016) reviewed data of 516 whom underwent CABG from June 2013 to December 2014; off those patients, 232 had CI cefazolin and 284 had INT cefazolin intraoperative. The researchers in this research found that there was no significant difference in terms of SWCs occurrence at harvest site in patients who had CI cefazolin or INT cefazolin (P=0.077). However, this result is weakening by the nature of the research design previously documented.

Based on each study' limitations, drawing a meaningful conclusion about the effective duration of prophylactic antibiotic that reduce the incidence of SWCs at harvesting site is difficult.

2.3.2.2 Use of Intraaortic Balloon Pump (IABP)

The perioperative use of intraaortic balloon pump (IABP) is considered to be a main predictor for SWCs at the harvest site post CABG (Riaz et al. 2008). IABP is used to assist the heart's perfusion by producing diastolic augmentation through a balloon that is placed in the descending aorta distal to the subclavian artery; this balloon is usually inserted via the femoral artery using a percutaneous or surgical arteriotomy and then introduced to the aorta by means of retrograde passage, IABP works by the concept of counter-pulsation, where the inflation and deflation of the balloon is synchronized (Riaz et al. 2008).

In the retrospective studies conducted by Palett et al. (2000) and Abbaszadeh et al. (2008), the use of IABP was significantly correlated with the occurrence of SWCs at the donor site; the P values were $P < 0.0001$ and $P < 0.035$ in Palett et al. (2000) and Abbaszadeh et al. (2008) retrospectively. However, as IABP is used only in certain cases, Palett et al. (2000) and Abbaszadeh et al. (2008) were the only studies that included them when investigating SWCs risk factors at the harvest site. There are many limitations that weaken the correlation between SWCs at the harvest site and the use of IABP in both studies; these limitations include the studies' design, as previously discussed, and the fact that the majority of patients in both studies who had IABP and developed SWCs were confounded by other risk factors like female gender, peripheral vascular disease and diabetes. Thus, the ability to consider the use of IABP as a main predictor for SWCs at the harvest site is limited.

2.3.2.3 Operative Techniques

2.3.2.3.1 Harvesting Method

There are three common harvesting methods that are widely used in clinical practice to harvest grafts such as the great saphenous vein and the radial artery for CABG (Lai et al. 2006). The first of these is the traditional open harvesting method where one continuous longitudinal incision is made at the donor site along the vessel, with the required length of the graft (Carpino et al. 2000). The second is the bridging method, in which several intermitted short skin incisions are placed along the required length of the graft, and the third is the endoscopic method, in which where only one short skin incision (3cm in length) is placed (Lai et al. 2006). Special equipment is required to conduct the latter technique to enhance visualization while harvesting, such as CO2 insufflation and camera (Carpino et al. 2000; Patel et al. 2001; Lai et al. 2006). Of these harvesting methods, continuous longitudinal incision is regarded as a risk factor for SWCs (Carpino et al. 2000).

Allen et al. (1998) in the US prospectively assigned 112 patients in random manner into two groups of harvesting techniques, namely a traditional longitudinal incision group and an endoscopic harvesting group, with 58 and 54 patients in each group respectively, to explore the association of harvesting method with SWCs post harvesting. They conducted a follow-up assessment of SWCs at two stages: the first stage was daily assessment by a qualified practitioner during the post-operative hospitalization period and the second stage was at six week post-operative. This RCT resulted in a significant reduction in SWCs in the endoscopic group, as only two patients from this group developed SWCs ($p < 0.02$), compared to eleven patients in the other group (East et al. 2013). Moreover, in the same geographical setting, Puskas et al. (1999) recruited 100 patients in their prospective RCT to investigate whether or not the endoscopic technique of harvesting the saphenous vein would result in fewer SWCs compared to the traditional open technique. With the use of an appropriate randomization method (a random numbers table), Puskas et al. (1999) randomly assigned their participants to an endoscopic vein harvest (EVH) group and an open vein harvesting (OVH) group (Parahoo 2014). After conducting follow-ups at two weeks and one month postoperatively, Puskas et al. (1999) could not detect any significant difference between EVH and OVH in terms of SWCs; however, the researchers did not declare this insignificant difference in numeric form, stating only that P= non-significant. This means that their claim is not meaningful, as stated previously (Salkind 2014).

In the UK in 2002, Blacka et al. conducted a study to investigate the effect of harvesting method on SWCs at the donor site. They prospectively randomized 40 patients into two groups, namely a minimally invasive group (bridging) and an open group, with 22 and 18 patients in each group respectively. The assessment of the harvest site wound was carried out at two stages, four days and at six weeks postoperatively. There was a significant reduction in SWCs in patients in the minimally invasive group at the first assessment stage ($P = 0.01$) but no significant difference in the second stage of the assessment ($P = 0.17$).

In Canada, Kiaii et al. (2002) conducted a prospective RCT to investigate whether endoscopic harvesting reduces SWCs; 144 patients were recruited in this study and distributed equally and randomly into two groups, namely the conventional and the endoscopic group. During the hospitalization period, three patients had SWCs, all of them from the open harvest group. Although, this finding favours the endoscopic method, this difference between harvesting groups was not statistically significant (P = 0.12). However, the difference between harvesting groups at six weeks post- operatively was highly significant, as sixteen additional patients from the conventional group developed SWCs compared to three patients from the endoscopic group (P = .0006).

Andreasen et al. (2008), in Denmark, investigated endoscopic and open methods for harvesting grafts in terms of the occurrence of SWCs. A total of 132 patients were recruited and randomly allocated to the intervention groups (endoscopic and open) using valid techniques such as sealed envelope and block randomization techniques (Houser 2015). In keeping with the RCTs discussed above, Andreasen et al. (2008) carried out the follow-up of patients at two stages: five days and one month post harvesting. This RCT revealed that SWCs occurred in 3% of patients in the endoscopic group and 27% in the open harvest group (P= 0.001).

As recently as 2016, Kalra et al. in India carried out a prospective RCT to assess the difference between harvesting methods (EVH and OVH) in terms of SWCs at the donor site. Kalra et al. (2016) used a random number table to assign fifty patients equally to EVH and OVH groups; using an appropriate technique for randomization will decrease the possibility of selection bias occurrence, increasing the validity of the results (Suresh 2011). Kalra et al. (2016) did not detect any significant difference between OVH and EVH in terms of SWC incidence (P<0.29). However, the details provided on the follow-up times were insufficient.

The majority of the RCTs discussed above suffer from many limitations that affect their power and weaken their results, such as low proportion of female participants, unjustified sample sizes and major risk of selection bias.

2.3.2.3.2 Wound Closure

Wound skin closure technique post harvesting can play a critical role in the occurrence of SWCs post vein harvesting (Hochberg et al. 2009). In 1997, Johnson et al. conducted a study in the USA to investigate the difference in SWCs between suture and staple skin closure techniques after CABG. They chose to conduct an RCT, which is the most appropriate design for their objective. A total of 242 patients, justified by power calculation, were recruited in their study and randomly assigned to the two closure methods. This RCT revealed a significant difference in the incidence of SWCs at the leg between both closure techniques, favouring the use of sutures for wound skin closure (P = 0.001). However, this RCT is tainted by the high possibility of selection bias due to the insufficient details on the randomization technique (Houser 2015).

The findings of Johnson et al. (1997) are in agreement with a previous RCT conducted at Cardiff by Angelini et al. (1984). In this RCT, Angelini et al. (1984) recruited 113 patients and distributed them to four different subgroups of leg wound closure methods in order to examine the effectiveness of these methods in terms of the incidence of SWCs. These closure methods are sutureless skin closure using "Op-site" (30 participants), continuous nylon vertical mattress suture (27 participants), metal skin staples (27 participants) and continuous subcuticular absorbable suture (29 participants). The overall prevalence of SWCs among the recruited sample was 4.5% and the authors noted that no SWCs were noted among the absorbable subcuticular group; thus, this RCT concludes by supporting the use of subcuticular closure in order to prevent SWCs. However, their initial sample size was not justified: therefore, it is not known whether or not the subgroup numbers were sufficient to meaningfully detect an effect (Houser 2015). In conclusion, the above-mentioned limitations limit the decision on which skin closure method can minimize the incidence of SWCs at the harvest site.

2.3.2.4 Level of Surgical Skills

Both harvesting and wound closure require a high level of surgical skill to ensure meticulous handling of the tissues which is required to achieve satisfactory surgical outcome (Campbell et al. 2008; Tan et al. 2012). This also supported by the variation in the outcomes of the RCTs that discuss harvesting methods, as this might indicate the impact of a high level of surgical skills in achieving satisfactory outcomes irrespective of the harvesting method being used. In many surgical interventions, surgeons' technical skills are more important determinants than wider issues of perioperative care in terms of outcomes such as the occurrence of SWCs (Reichman and Greenberg 2009; Alali 2016).

In the UK, Mishriki et al. (1990) investigated consecutive 702 patients in different surgical specialty to determine the incidence of SWCs and their contributory factors. Mishriki et al. (1990) classified the surgical wounds to "'clean' (operations in which a viscus was not entered), 'clean-contaminated' (in which a viscus was entered but without spill of contents), 'contaminated' (in which gross spill occurred or in which inflammation without pus formation was encountered) and 'dirty' (where free pus was drained)". As SWCs aetiologies are multifactorial, regression analysis was used by researchers in order to determine their individual significance (Salkind 2014). The study implies that there is a highly significant association between the individual operator and the occurrence of SWCs in the clean wound category (P< 0.001). However, the accuracy of this strong association is decreased due to the possibility of type I error because the sample size was not justified (Salkind 2014).

In 2004, Hall and Hamilton developed a model to describe surgeons' performance against absolute standards in the US; this model is known as the Bayesian hierarchical bivariate probit model. Hall and Hamilton (2004) applied this model to 2,578 patients who had received care from any of 36 surgeons in different specialties at a large hospital and resulted in a wide variation among surgeons in terms of the 30-day mortality and 30-day morbidity such as SWCs in their patients, indicating that the increase in the volume of the individuals' procedures may improve their surgical outcomes. However, although Hall and Hamilton (2004) counted the cases for each surgeon, they did not consider the location of surgery because many surgeons operated at different hospitals; therefore, the effect of hospital-specific surgeon volume on clinical outcomes was not examined, and this might bias their results (Schrag et al. 2002).

Furthermore, a prospective cohort study was conducted in the US by Killian et al. (2001) in order to investigate SWCs post caesarean section; 765 patients who had caesarean sections at their centre during 6-month periods each year from 1996 to 1998 were recruited for this investigation. One of the factors associated with SWCs that was detected by Killian et al. (2001) is prolonged operative time, which was related to the level of surgeon's skills (P= 0.04). However, this significant association might be confounded by female gender, which is discussed earlier as a risk factor for SWCs. In the same geographical setting in 2008, a retrospective case-control study was conducted by Olsen et al. to investigate the associated exposures with SWCs occurrence following low transverse caesarean sections; Olsen et al. (2008) reviewed 1,605 women who had undergone this surgery. Five percent of those patients developed SWCs. In order to minimize the risk of confounding variables of the associated exposures, Olsen et al. (2008) calculated adjusted odds ratio (aOR). They found that poor surgical skills were associated with SWCs (aOR = 2.7 [95% CI, 1.4- 5.2]). When the (OR >1), it means that the exposure is associated with higher odds of the dependent variable (Szumilas 2010). As previously stated, this study design poses limitations that decrease the accuracy of this association; these limitations include selection bias and accuracy of documented data (Parahoo 2014).

Hubner et al. (2011) conducted a multicentre prospective cohort study to examine the role of the level of surgeon's experience in the occurrence of SWCs post colon surgery in Switzerland. This study resulted in a suggestion that the experience of the surgeon may constitute a main predictor for the occurrence of SWCs post colon surgery; the authors emphasized that a high level of surgical skills will facilitate the adherence to guidelines which are needed to have satisfactory outcomes.

Birkmeyer et al. (2013) have conducted primary research prospectively to examine the association between the level of surgical skills and postoperative clinical outcomes in bariatric surgeries. Birkmeyer et al. (2013) have used a valid tool such as "Peer Rating of Surgical Skill" to categorize surgeons (Finks et al. 2011). According to quartiles of skill ratings, surgeons were categorized into three groups: "the bottom group (first quartile), middle group (second and third quartiles), and top group (fourth quartile)". The researchers in this study found that a high level of surgical skills were associated with fewer postoperative complications (P = 0.01). Recently, Sahni et al. (2016) hypothesized that surgical outcomes are independently related to operators' experience with that specific procedure. They conducted a retrospective study to analyse Medicare data of (695,987) patients who had undergone a variety of different cardiothoracic and vascular surgeries from 2008 to 2013 at different hospitals within the USA by 25,152 surgeons in order to test their hypothesis. Sahni et al. (2016) concluded by supporting their hypothesis.

In summary, the involvement of surgical operators is considered to be a potential exogenous factor for the occurrence of SWCs; therefore, a high level of operators' skills is essential to achieve satisfactory surgical outcomes irrespective of the type of surgical procedure.

2.4 Summary of the literature

The current literature on the contributory factors to SWCs after long saphenous vein or radial artery harvesting in CABG suggests that endogenous factors such as female gender, increase in age (≥ 60 years), obesity (> 30 kg/m2), diabetes, peripheral vascular disease, chronic renal insufficiency, congestive heart failure and tobacco smoking, and exogenous factors such as operative techniques, use of an intra-aortic balloon machine and appropriate use of prophylactic antibiotics are found to be independent predictors. However, the decision on whether or not these factors are main predictors for SWCs at harvesting sites remains equivocal due to the limitations of the majority of studies reviewed in this chapter, such as methodological flaws and small sample size.

Although a high level of operators' surgical skills plays a critical role in reducing the incidence of SWCs, as previously stated, the current literature undervalues the significance of the level of operators' skills in limiting the occurrence of SWCs because none of the studies identified in this chapter have independently investigated the association of operators' skills with the incidence of SWCs at the harvesting site.

To the researcher's knowledge, only Birkmeyer et al. (2013) have conducted primary research prospectively to examine the association between the level of surgical skills and postoperative clinical outcomes in bariatric surgeries. Thus, this observational research is carried out to illustrate the association between the use of operators (physicians' assistants and medical doctors) and the occurrence of SWCs at graft harvesting sites in CABG at the researcher's hospital in KSA. By illustrating this association, the results of this research may add value to the literature by adding new knowledge to the factors associated with SWCs following conduit harvest; this new knowledge could be used to form new strategies that can be utilised to minimise or avoid SWCs after graft harvest in CABG. In addition, the outcome of investigating the involvement of physicians' assistants will help to facilitate the establishment of a practical environment that will enable physicians' assistants to optimize their expertise to provide a high quality of care services and maximize patient safety (Hughes 2008).

3. Methodology

This research was a retrospective chart review cohort study to explore the association between the involvement of physicians' assistants and physicians and the occurrence of SWCs at harvesting sites post CABG at King Abdullah Medical City (KAMC) in Kingdom of Saudi Arabia. Junoda and Elger (2010) documented a significant increase in the amount of medical research and healthcare research that is conducted retrospectively on patient data. The use of retrospective chart review in healthcare-based disciplines is a very common research methodology (Matt and Matthew 2013). Thus, this type of study plays a significant role in medical and healthcare research (Stefánsson et al. 2008). In many cases, retrospective studies are used to discover or to confirm important facts in healthcare sciences (Song and Chung 2010).This study adopts a quantitative methodological approach, as it seeks to determine the associations between study variables (Babbie 2015).

3.1 Study Design

As this study is conducted to explore the association, if any, between the involvement of different surgical operators (physicians' assistants and medical doctors) and the occurrences of SWCs at harvesting sites post CABG, a prospective observational cohort study is the most applicable design to conduct this research (Mann 2003). However, as previously stated, SWCs become evident on average 21.5 days after harvesting, so a prospective cohort design was not practical in the present study due to the time constraints on the researcher. Therefore, this research was conducted as an observational retrospective study. Hess (2004) supported the use of retrospective research when it is not feasible to carry out a prospective study. Song and Chung (2010) stated that observational studies with retrospective design can provide meaningful results if conducted properly.

Observational studies can be performed using many designs, such as cohort, case control and cross-section designs (Mann 2003). However, cohort and case control observational designs are the only two primary forms that can be used to evaluate the associations of outcomes and exposures (Song and Chung 2010). The difference between these designs is that if researchers wish to examine the outcome of interest and look for the associated exposures, they must choose a case-control design; but if they want to examine a specific exposure to find out whether it is associated with the occurrence of the outcome of interest, they must choose a cohort design (Mann 2003). Subjects in retrospective cohort studies are identified based on a specific clinical feature that was determined in the past and both exposures and outcomes are collected at the same time (Thadhani and Tonelli 2006). Thus, in order to answer the present study's research question, a retrospective cohort design is chosen.

Song and Chung (2010) documented that retrospective cohort research requires fewer resources in general and it is relatively quick compared with other studies' designs. On the other hand, one of the major limitations that weaken this design is the high possibility of selection bias, as previously stated: therefore, to avoid and minimize this risk, a clinical supervisor and two independent reviewers were recruited and assigned to this research (Parahoo 2014). However, since this research was conducted using patients' medical charts, there are some limitations that cannot be avoided, as documented by Wickson-Griffiths et al. (2014), including the availability of medical records and the accuracy of the documented data.

This retrospective cohort study was carried out as a pilot study mainly because to the author's knowledge, this was the first study to be conducted to explore the operators' effects on the incidence of SWCs at harvesting sites post CABG (Hertzog 2008). Pilot studies are significant in all healthcare study designs for purposes such as the determination of the required sample size and the evaluation of the instruments to be used (Gearing et al. 2006).

3.2 Study Variables:

The study variables were divided into three groups, namely independent, dependent and confounding variables. The investigated exposures (physicians' assistants and medical doctors) were set as independent variables: according to Al-Riyami (2008), independent variables are those variables that are manipulated in a study in order to find out their effect on the outcome of interest. As the dependent variable is defined as the outcome of interest, the presence of SWCs at the harvesting site after CABG was the dependent variable (Al-Riyami 2008). As previously stated, hematoma, seroma, infections and wound dehiscence are the most common forms of SWCs after graft harvesting; thus, if any of these complications' criteria were documented on patient records, they were counted as SWCs. The criteria for these SWCs were defined in details in the first chapter of this work.

All of the endogenous factors (female gender, increase of age (≥60), diabetes mellitus (which is defined as hemoglobin A1c level ≥ 6.5% or the use of anti- hyperglycemic medications to treat diabetes documented in patient records), either controlled (postoperative glycemic range between 140 and 180 mg/dL) or not controlled (postoperative glycemic >180 mg/dL), peripheral vascular disease, chronic renal insufficiency (creatinine >2 mg/dL or history of renal failure is documented in patient chart), obesity (BMI ≥30 kg/m2), congestive heart failure (ejection fraction which is defined as the percentage of blood ejected by the heart each beat (EF) < 40%), and tobacco smoking status), and exogenous factors (operative techniques (open graft harvesting and endoscopic graft harvesting) and the use of an intra-aortic balloon machine) were documented to be considered as confounding variables. According to Riyami (2008), confounding variables are those that might influence the effect of independent variables on the dependent variables. The criteria of comorbidity variables were defined in accordance with the Kidney Disease Improving Global Outcomes Working Group guidelines (2012), the New York Heart Association and the Society of Thoracic Surgeons.

As noted, the use of prophylactic antibiotics and the method of wound closure were not considered to be among the confounding variables in this research: this is because all CABG patients at KAMC received the same dose of prophylactic antibiotics and the suture technique is the only closure technique used to close wounds post conduit harvest.

The above identified variables were operationalized as described by Sharma et al. (2009), Ledur et al. (2011), East et al. (2013) and Gaballah and Abo Elnor (2013). Gearing et al. (2006) stated that when researchers conducting a retrospective chart review have identified study variables, they must conduct a literature review to facilitate comprehensive understanding of how other investigators have operationalized these variables. This will improve the validity and reliability of the variables under investigation by enabling researchers to adopt an appropriate approach to address a particular study question (Worster and Haines 2004).

3.3 Population and Selection Criteria:

The individuals who are the main focus of scientific query in any research are called the research population (Banerjee and Chaudhury 2010). This study's population consisted of all patients with coronary artery disease who underwent CABG surgery between March 2013 and November 2016. It is essential to define the time frame in a cohort study to facilitate the investigation of the members of the cohort who have been exposed to a particular variable (Mann 2003). The chosen time-frame was based on the fact that the registration system for cases at the Cardiac Centre in the KAMC started in March 2013.

Inclusion and exclusion criteria should be stated sufficiently in order to yield data that produce meaningful results, increasing the external validity of the study (LoBiondo- Wood and Haber 2014). All CABG patients who underwent long saphenous vein or radial artery harvesting were eligible for inclusion. As some surgeons do not prefer to use the long saphenous vein or the radial artery as bypass grafts in CABG surgery, all CABG patients who underwent only bilateral mammary artery harvesting were excluded from this study (Di Mauro et al. 2014). In addition, eligible charts were excluded if sufficient lack of variables was recorded. 76 notes were excluded because the harvesting was started by medical doctors and finished by physicians' assistants: thus, to remove confusion, these notes were removed from the sample.

Determining the required number of individuals prior to conducting any quantitative research is an essential step for ethical and cost purposes (Houser 2015). Thus, calculating the sample size in this study is crucial to set the limit for the minimum numbers of required medical notes to garner sufficient power (Jones et al. 2003; McCrum-Gardner 2010). However, as the odds ratio of identified exposures is unknown, this prevents the calculation of the sample size in this study (Hajian-Tilaki 2011). Thus, this retrospective cohort study is carried out as a pilot (Hertzog 2008). The availability sampling method was used to select eligible patients' records within the identified timeframe. This sampling method is known as convenience sampling which is the most common sampling method used in retrospective records review researches: convenience sampling technique is a type of non-probability sampling method (Suen et al. 2014; Wickson-Griffiths et al. 2014). A final sample of 200 notes was included in this research, as they fulfilled the above eligibility criteria in the identified time frame.

3.4 Data Collection Procedures:

When conducting any research involving a chart review, the use of an abstraction form will help to reduce errors in data collection by guaranteeing a measure of consistency among the data abstractors (Matt and Mathew 2013). Thus, choosing a suitable data abstraction instrument that is clear and well-organised is of immense importance (Sarkar and Seshadri 2014). There are two different types of data abstraction instruments: paper and electronic (Gearing et al. 2006). An electronic abstraction tool was chosen for this study; the selection was based on its advantages, such as reduced possibility of input errors, easier data access and cost effectiveness (Gearing et al. 2006).

The chosen abstraction tool was created and designed specifically for the purpose of this research. Gearing et al. (2006) recommend designing spread sheets for retrospective chart review studies. The key to designing this study's abstraction form was to facilitate logical organization of the various variables involved in the research. Banks (1998) suggested that when researchers are designing an abstraction form, the simplicity of variables' organization should be ensured to facilitate the gathering and interpretation of the data, regardless of the type of abstraction form. In addition to the abstraction form, the researcher also created manual abstraction procedures, which included steps for data extraction, explanation of the protocols and data abbreviations as well as shorthand symbols; this was to ensure accuracy, reliability, and consistency for all data abstractors (Banks 1998).

There were three data abstractors in this research, including the researcher. The researcher, who created and designed the data abstraction tool, provided the other data abstractors with adequate training on the data abstraction form, the study variables, the procedural manual and inclusion and exclusion protocols. Such training is recommended when conducting retrospective chart review studies to avoid compromising the validity of the data (Worster and Haines 2004). In addition, sufficient training of data abstractors will reduce the risk of errors that may result from variability in coder interpretation (Sarkar and Seshadri 2014). Furthermore, adequate training can ensure criteria standardization among all data abstractors, which is essential to produce sound quality of data (Matt and Mathew 2013). For example, the decision on which charts were to be included and excluded was made by all abstractors. However, none of the data collectors were blinded to this research purpose and question. As rightly stated by Gearing et al (2006, p. 129):

"Abstractors blind to the hypothesis decrease reviewer bias, specifically the possibility of their assessment being swayed by knowledge of others (e.g., investigators), concern over adversely affecting the study's outcome, or interpreting their abstraction as too lenient or harsh."

The data collection activities were carried out at King Abdullah Medical City (KAMC) in the medical record department in Mecca, Saudi Arabia. Gearing et al. (2006) emphasized that the data needed in retrospective research have often already been recorded for other reasons. The data collected in this retrospective research already existed in patients' notes for the purpose of patients' care.

The data collection was conducted in five phases, starting with holding a meeting on Sunday 2nd April 2017 between the researcher, the clinical supervisor and other data abstractors to discuss and finalize the data collection sheet and to review the selection criteria. Following this meeting, on the same day, the second phase of the data collection procedure started by identifying the eligible medical records; this process took five working days (08:00 – 16:00). The third phase was to conduct piloting of 10% of the total sample (20 charts) in order to be familiar with the abstraction process and to make decisions about ambiguous information: this phase took two days. The fourth phase was a meeting with the clinical supervisor to discuss the pilot study. The final phase involved the collection of data from all eligible medical records this stage lasted from 10th April to 30th April 2017 (See appendix 3.B)

The different types of study characteristics were gathered and organized in a spread sheet in the Excel® program for Windows® XP: as suggested by Allison et al. (2000), gathering data in this form facilitates logical organisation. The required data were double entered to ensure data quality, as recommended by Gliklich et al. (2014) (See Appendix 3.C).

3.5 Ethical Considerations:

The integrity and credibility of any research are correlated with its handling of ethical aspects (O'Leary 2010). Thus, researchers must ensure that their study is ethical (Robson 2011). In order to maintain the ethical principles and to ensure safe practice prior to conducting this study, ethical approval was obtained from the Cardiff University Research Review Ethics Committee and the Ethical Review Board Committee in the researcher's hospital in Saudi Arabia, having provided a clear proposal that set out all stages of the research steps, including the aims, methodology and handling of the sample (Parahoo 2014) in line with the boundaries set out by the respective ethics committees (O'Leary 2010) (See Appendix 3.D).

Robson (2011) stated that researchers are legally obligated to comply with human rights when conducting any research involving either human subjects or their attributes. Human rights are defined by Burns and Grove (1999, p.157) as "claims and demands that have been justified in the eyes of an individual or by the consensus of a group of individuals".

Some rights, such as self-determination, confidentiality, protection from harm and fair treatment, are connected to human rights in research (Burns and Grove 1999).

The risk assessment was calculated and resulted in a low risk and no further action to be undertaken. Thus, the risk was minimal in this study, since it involved only a retrospective records review: no intervention was applied and there was no direct contact with the participants (LoBiondo-Wood and Haber 2014). The only human participants in this research were in the form of medical notes; nonetheless, loss of participants' private and personal information and staff information was considered as a potential risk because of the researcher's access to such information (Gearing et al. 2006). Therefore, in order to maintain confidentiality and privacy and to fulfil the ethical requirements, numbers were used to identify the patients (Robson 2011). Treating data anonymously is one of the main criteria that should be considered in retrospective chart review (Elger 2010). In addition, O'Leary (2010, p. 42) emphasized that anonymity "goes a step beyond confidentiality", as it prevents identification of the participants even by the researcher. Although the abstraction form designed for this study included no personal information that could reveal patients' or staff's identities, complete anonymity was not guaranteed in this research, as the researchers collected and reviewed the data, as previously stated. Robson (2011) stated that complete anonymity will not exist unless data cannot be linked to the participants (See Appendix 3.E).

Collecting data for the purpose of fulfilling academic requirements can cause ethical issues. As stated by Robson (2011), several potential problems can arise, such as dishonesty or fabrication of data that are relevant to the student's project. Thus, in order to increase the accuracy of the data, the author's clinical supervisor was assigned to check and review the gathered data (Punch 2005). In order to comply with the Data Protection Act 1998, the gathered data were stored electronically on a password-protected device (Redsell and Cheater 2001).

3.6 Data Analysis:

In order to conduct the statistical analysis, the raw data were imported from Excel® to the Statistical Package for the Social Sciences (SPSS), which is an appropriate tool for quantitative healthcare research (Parahoo 2014). Both types of statistical analyses (descriptive and inferential) were undertaken using SPSS.

SPSS is able to perform numerous different types of statistical tests: thus, to yield legitimate findings, the selection of suitable tests is essential (Dakhale et al. 2012). There are three fundamental issues that the researcher must consider to facilitate the correct analytical approach: the level of the data being collected, the nature of the data distribution and the type of research question being asked (Bhalerao and Parab 2010; Nayak and Hazra 2011). A test of normality was not required in this research, mainly because the data in this study was categorical (Mu et al. 2012). Although age and BMI are considered to be quantitative (numerical) data, they were transferred to categorical form in order to understand their particular relationship with SWCs (Blaikie 2003). Age was categorized into two categories (≥60 and <60 years): this classification was based on studies conducted by Thomas et al. (1999), Olsen et al. (2003) and Sharma et al. (2009). On the other hand, BMI was classified into non- obese and obese (<30 and ≥30.00 kg/m^2) respectively (Kopelman 2000).

Descriptive statistics were used to summarize the samples' basic features in a meaningful manner to facilitate simpler interpretation of the data (Spriestersbach et al. 2009). Therefore, the mode and percentile were used to describe the categorical data (Salkind 2014). In order to facilitate interpretation, tables and pie figures were used to summarize the data; these are the most popular ways of presenting categorical characteristics (Spriestersbach et al. 2009). To verify the difference between the cohorts under investigation (physicians and physicians' assistants groups), the Chi-square ($\chi 2$) test was used. Chi-square ($\chi 2$) is a distribution-free test that is used to evaluate the relationship between categorical variables (McHugh 2013).

In order to test and measure the association between SWCs and all above stated variables, chi-square ($\chi 2$) and binary logistic regression were used respectively. Binary logistic regression is an analytical approach which is used when the researcher wants to assess the relationship between dichotomous dependent variables and categorical independent variables (Strömbergsson 2009). The odds ratio (OR) was calculated to determine the magnitude of the exposure' association with the occurrence of SWCs (Grimes and Schulz 2008). Szumilas (2010, p. 227) defined the OR as "a measure of association between an exposure and an outcome". The OR value will be interpreted as follows: "OR=1: exposure does not affect odds of outcome. OR>1: exposure associated with higher odds of outcome. OR<1: exposure associated with lower odds of outcome" (Szumilas 2010, p. 227).

A 95% confidence interval (CI) was used to indicate the uncertainty level around the effects measured (Strömbergsson 2009). All statistical values were considered significant at $p \leq 0.05$. In order to perform the statistical tests appropriately to yield legitimate results, advice was obtained from statistical support provided by Cardiff University.

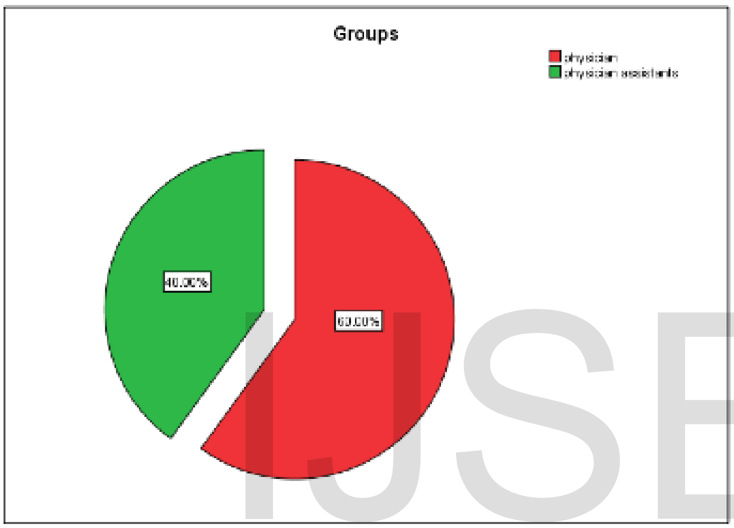
4. Results

4.1 Descriptive Statistics:

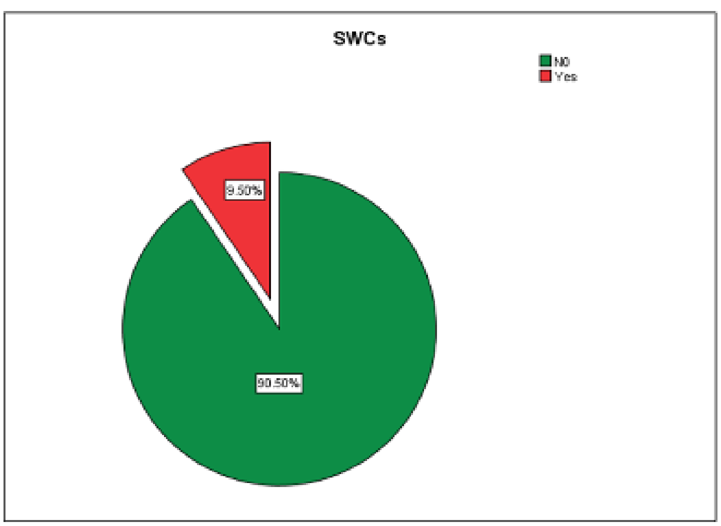
Two hundred patients were included during this study period (March 2013 and November 2016. Of this sample, 167 patients (83.5%) were male and 33 (16.5%) were female (see Figure 4.1). The mean age was 58.99 years (SD= 9.426); 48% (96 patients) met the criteria for "increased age" (≥ 60 years. The majority of the participants were diabetics (163 patients: 81.5% of the sample); 6.5% of the diabetic population (13 patients) met the criteria for uncontrolled diabetes. Twenty-six patients had congestive heart failure, accounting for 13.0% of the whole population.

Only eight patients (4.0%) from the entire cohort suffered from peripheral vascular disease (see Figure 4.6); the same number of different patients suffered from chronic renal insufficiency (see Figure 4.7). Smokers constituted 54% of the sample (108 patients). The mean BMI for the sample was 28.29 kg/m^2; however, only 76 patients (38.0%) met the criteria for obesity (BMI > 30 kg/m2) (see Figure 4.9). The intra-aortic balloon catheter was used in 30 patients (15%). The majority of this research population (166 patients: 83%) had their conduits harvested using an endoscope.

Eighty patients (40%) from the cohort underwent peripheral conduit harvest by physician assistants, while 120 patients (60%) had their peripheral conduits harvested by physicians. Overall, 19 patients (9.5%) from the entire cohort developed SWCs; 13 of them were from the physicians' cohort, representing 68.4% of all SWC patients, while only six patients from the physician assistants' cohort developed SWCs, accounting for 31.6% of the SWC population.



The operators' groups



Surgical Wound Complications (SWCs)

Table 4.1: Summary of the descriptive statistics:

Variables	Frequency	Percentage
Male	167	83.5%
Female	33	16.5%
"Increased age" (≥ 60 years).	96	48%
Obesity (BMI > 30 kg/m2)	76	38.0%
DM	163	81.5%
UDM	13	6.5%
PVD	8	4.0%
Smokers	108	54.0%
OVH	34	17.0%
EVH	166	83.0%
CHF	26	13.0%
IABP Use	30	15.0%
Physician' cases	120	60%
physician assistants' cases	80	40%

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SWCs incidence	19	9.5%

(DM = diabetes, UDM = uncontrolled diabetes, PVD = peripheral vascular disease, CRI = chronic renal insufficiency, CHF = congestive heart failure, IABP= intra-aortic balloon pump, OVH= open vessel harvesting, EVH= endoscopic vessel harvesting, SWCs= surgical wound complications).

5. Discussion

5.1 Interpretation of Findings:

The ultimate goal of this retrospective research was to examine the association of the involvement of surgical operators with different training and education (physicians and physicians' assistants) with the occurrence of SWCs after long saphenous or radial artery harvesting in CABG at KAMC. This associated factor has not previously been examined in the literature. Additionally, a range of other factors that are potentially associated with the occurrence of SWCs at harvest sites post CABG were explored and examined in order to utilize this knowledge to develop strategies to avoid and/or minimize the incidence of SWCs. To provide a comprehensive discussion of the findings, all of the investigated variables will be discussed under separate subheadings.

5.1.1 Surgical Operators:

The results of this research revealed that physicians' assistants can provide comparable care to that provided by physicians in terms of their influences on the occurrence of SWCs at the harvest site when they are utilized to harvest peripheral conduits as grafts for CABG (*P* = 0. 472, OR = 0.119 [95% CI, 0.112 - 1.502; *P*= 0 .427, OR = 0.191 [95% CI, 0.632 - 1.439] for physicians and physicians' assistants respectively). This result is not surprising and is consistent with the only other study in the literature regarding the efficiency of physicians' assistants in cardiac surgery as first assistants to surgeons (Ranzenbach et al. 2012), who concluded that physicians' assistants can function safely and efficiently when assisting surgeons. In addition, this study's findings are also supported by other studies conducted to investigate the quality of patient care provided by physicians' assistants in other surgical specialties. In an OBGYN setting, Goldman et al. (2004) concluded that complication rates after surgical abortions performed by physicians' assistants were comparable to those provided by physicians. Whilst in Trauma settings, Bevis et al. (2008) identified no differences in insertion complications or complications requiring additional interventions between tube thoracotomies performed by trauma surgeons and physicians' assistants. Furthermore, Althausen et al. (2013) concluded that the use of physicians' assistants is beneficial to patients, physicians and hospitals; this conclusion was a result of research conducted to examine the true impact of the involvement of physicians' assistants compared with trauma surgeons in the US.

Combined this evidence suggests degree of equivalence between roles over an extended period of time.

Even in the wider non-surgical medical literature, physicians' assistants have been found to provide quality patient care in a variety of practice areas and settings (Hooker et al. 2007). In the cardiology setting, Krasuski et al. (2003) conducted a prospective study to evaluate the safety of physician assistants in carrying out cardiac catheterization compared with cardiology fellows-in-training; they found that the complication rates resulting from diagnostic cardiac catheterization, including coronary angiography, were similar between physicians' assistants and cardiology fellows-in-training. Furthermore, in the primary care setting, Drennan et al. (2015) conducted a study to compare the effectiveness of physicians' assistants when providing same-day requested consultations to those provided by general practitioners in terms of re-consultation within fourteen days for the same or linked problems; this observational study was carried out within the NHS in England and revealed no significant differences in the rates of re-consultation, stating that physicians' assistants are an "efficient addition to the general practice workforce". It is important to note that this recent study conducted by Drennan et al. (2015) was consistent with an earlier seminal study conducted by Sox (1979), who evaluated the quality of patient care provided by physicians' assistants and nurse practitioners compared to that provided by medical doctors in the US from a ten-year perspective. In this study, Sox (1979) found that physicians' assistants and nurse practitioners produced equivalent outcomes to doctors when treating patients in primary care.

Although, the incidence of SWCs was not statistically different between the cohorts of physicians and physicians' assistant (P= 0.472), this study suggests that the clinicians' increased procedural volumes are associated with better surgical outcomes. This suggestion inferred from the fact that the patients in the physician assistants' cohort had lower incidence of SWCs (6 (7.5%)) compared to those in the physician' cohort (13 (10.8%)) even though the patients were not statistically different in terms of demographic and perioperative risk factors. The 80 patients in the physicians' assistants' group were operated on by only two physicians' assistants, both of whom have a minimum of five years' experience; while, in the other group, the 120 patients were operated on by six physicians with experience ranging from two to ten years. The physicians' assistants in the KAMC, as in many other hospitals, work only in operating theatres and are not involved with duties in wards or intensive care units, while the duties of all six physicians rotate between outpatients' clinics, wards, intensive care units and operating theatres (Mulholland et al. 2006). Morgan et al. (2008) argued that, the physicians' assistant have extensive experience of a limited group of activities, but can address issues in this area very effectively, as opposed to the physicians who have a wider range of experiences and can draw on those experiences to more widely inform their decision making process. The current study' suggestion (the clinicians' increased procedural volumes are associated with better surgical outcomes, i.e. the greater the level of experience, the better the outcomes) appears to be in agreement with the body of evidence from previously identified studies, the majority of which were prospective (Mishriki et al. 1990; Killian et al. 2001; Hubner et al. 2011; Birkmeyer et al. 2013), with the most recent being retrospective studies conducted by Olsen et al. (2008)

and Sahni et al. (2016).

As previously outlined, other than the involvement of surgical operators, there are other potential influences on SWCs following peripheral conduit harvest in CABG. This study's results confirmed that some influences were independently associated with SWCs, while others were not. Thus there are clearly areas of agreement and conflict between the results of this current study and the existing evidence base. The following paragraphs will comprehensively discuss these issues.

5.1.2 Female Gender

Female sex was significantly associated with SWCs (P =. 044; OR = 0.195 [95% CI, 0.040 - .955). This was consistent with the studies discussed above conducted by Vuorisalo et al. (1998), Carpino et al. (2000), Paletta et al. (2000), Swenne et al. (2004), Kayacioglu et al. (2007), Abbaszadeh et al. (2008) and Gaballah and Abo Elnor (2013). There are two possible explanations that may explain why females are more prone to the occurrence of SWCs post-harvesting, namely anatomical and physiological features. Anatomically, women have smaller peripheral arteries than men, which may lead to wound healing impairments, resulting in SWCs (Vouyouka and Kent 2007). As noted in this the population for this research, the majority of women with SWCs can be classified as postmenopausal (<45 years): this physiological feature can cause delays in wound healing, and as a consequence, may result in SWCs. Abbaszadeh et al. (2008) discussed that the decrease in the level of estrogen may impair leg wound healing. Calvin (2000) emphasized that estrogen plays a significant role in the quality and maintenance of skin in females: therefore, estrogen may play a pivotal role in surgical wound healing. Shanker et al. (1995) showed that the administration of estrogen increases the release of platelet-derived growth factor alpha, which is required to stimulate fibroblastic and myofibroblastic wound contraction.

5.1.3 Age

Increased age (≥ 60 years) as a demographic risk factor for SWCs post-harvesting was not found to be independently significant in the occurrence of SWCs in this study (P = 0.343; OR = 0.505 [95% CI, 0.131 - 1.949]) as shown in Table 4.3 This result conflicts with those of Thomas et al. (1999), Olsen et al. (2003) and Sharma et al. (2009) who found that the older patients were more prone to SWCs at the harvest site. This may be because of the difference in intraoperative characteristics between this study's sample and theirs: for this study the majority of patients who were categorized as older patients had their conduits harvested with the use of an endoscope, while in the studies conducted by Thomas et al. (1999) and Olsen et al. (2003), the traditional open method of harvesting was used exclusively, and Sharma et al. (2009) used this method for the majority of their patients. However, more detailed discussion of harvesting techniques as potential confounders follows.

5.1.4 Congestive Heart Failure

With the exception of Sharma et al. (2009), this study found no significant association between congestive heart failure and the occurrence of SWCs (P = 0.486; OR = 0.558 [95% CI, 0.108 - 2.874]). Although Sharma et al. (2009) deduced an association between congestive heart failure and the occurrence of SWCs at harvest sites, no justification was provided to explain the significance of this association (P= 0.004). Therefore, the explanation of this conflict with Sharma et al. (2009) is not clear. One possible explanation of this contrast from the perspective of this current research is that Sharma et al. (2009) investigated both sternal and harvest site complications following CABG. However, in the absence of a clearly identified rationale, the claimed statistical significance for this alleged associated by Sharma et al. (2009) is questionable. It is well documented that congestive heart failure is an independent risk factor for sternal wound complications. Therefore, it might be possible that SWCs at the harvest site were secondary to sternal SWCs, as a result of the patients' psychological stress caused by sternal SWCs due to concerns such as long-lasting disability or prolonged recovery (Pinto et al. 2016).

5.1.4.1 The impact of stress response

Numerous studies have confirmed that stress has a great impact on compromising surgical wound healing; this is because stress can induce the disruption of neuroendocrine immune equilibrium (Glaser and Kiecolt-Glaser 2005; Vileikyte 2007). Research relates the negative impact of the stress on wound healing to its effects on cellular immunity (Godbout and Glaser 2006; Sternberg 2006). Cellular immunity regulates the production of pro-inflammatory and anti-inflammatory cytokines, which regulate wound healing; the stress' pathophysiology results in deregulation of the immune system through the sympathetic-adrenal medullary and hypothalamic-pituitary- adrenal axes (Boyapati and Wang 2007). Therefore, this psychological stress effect results in impairment of the normal cell-mediated immunity at the surgical wound site, causing a significant delay in the wound healing process, which leads to SWCs. Stress can also indirectly affect the process of wound healing: according to Keylock et al. (2008), stress can lead to sleep disruption, which diminishes the production of growth hormone.

5.1.5 Obesity

Although Spelman et al. (2000), Olsen et al. (2003), Kayacioglu et al. (2007) and Sharma et al. (2009) documented obesity (BMI > 30 kg/m2) as an independent risk factor for SWCs post-harvesting, the findings of this research conflict with this claim. All of these studies justified their results in terms of the significant alteration of the blood circulation that results from anatomical alterations caused by obesity: when excess adiposity is developed, a new vascular system is developed to adapt to the increased demand on the circulation. However, these developments are not met with a corresponding increase in heart function, leading to insufficient blood delivery, which in turn can lead to the development of SWCs (Pierpont et al. 2014). However, in this research, obesity (BMI > 30 kg/m2) was not independently associated with the occurrence of SWCs (*P* = 0.972, OR = 1.038 [95% CI, 0.131 - 8.201]). This is in agreement with Abbaszadeh et al. (2008) and Gaballah and Abo Elnor (2013). There are two possible explanations for this result: the first is the concept that isolated obesity by itself does not cause poor heart function; this concept is known as the "obesity paradox" and is defined by Amundson et al. (2010; p.1) as: "The observation that, although obesity is a major risk factor in the development of cardiovascular and peripheral vascular disease, when acute cardiovascular decompensation occurs, for example, in myocardial infarction or congestive heart failure, obese patients may have a survival benefit".

The second possible explanation for the inverse association of obesity and occurrence of SWCs at harvest site in this research is that the majority of obese patients in this research had their conduits harvested through the use of an endoscope, while surgeons in Spelman et al. (2000), Olsen et al. (2003), and Kayacioglu et al. (2007) exclusively used the open technique for harvesting grafts. Only Sharma et al. (2009) used the endoscopic technique for small samples of their entire cohort. However, it is important to note that whilst this and all other studies were consistent in the use of BMI as a measure of obesity, there is inconsistency in their findings regarding the actual effect of obesity on the occurrence of SWCs. Gurunathan and Myles (2016) argued that the use of BMI to describe obesity can result in inaccurate adiposity assessment, mainly because BMI does not distinguish fat mass from lean muscle, and thus fails to address the issues of alterations to vascular anatomy associated with adiposity. Thus a potentially significant variable in wound healing is not appropriately addressed.

5.1.6 Diabetes Mellitus

The majority of patients in this research sample suffer from diabetes mellitus (163 patients: 81.5% of the sample). Although this percentage appears high, it is not unexpected, because diabetes mellitus is a well-known independent risk factor for the development of coronary artery disease (Al-Nozha et al. 2016). Diabetes is well documented for its effects on the vascular system, causing atherosclerosis (hardening of the arteries); this in turn negatively influences surgical wound healing, causing SWCs in general (Guo and DiPietro 2010).

However, the presence of diabetes was not significantly associated with the occurrence of SWCs in this research (*P* = 0.901; OR = 1.107 [95% CI, 0.223 - 5.486]), as shown in Result Table 4.3: this might be related to effective hyperglycaemic control prior to surgery. On the other hand, predictably, uncontrolled diabetes mellitus was significantly correlated with SWCs at the harvest site (*P* = .004; OR = 0.072 [95% CI, 0.012 - 0.422]). This was consistent with the findings of Thomas et al. (1999), Paletta et al. (2000), Spelman et al. (2000), Brandt et al. (2004), Kayacioglu et al. (2007) and Sharma et al. (2009). This significant correlation can be explained by the effect of hyperglycemia on the cellular response to tissue injury (Kolluru et al. 2012). Hyperglycaemia in patients with poor glycemic control can lead to higher concentration of glycosylated haemoglobin: this leads to poor oxygen delivery at the capillary level due to its increased affinity for oxygen (Wukich 2015). Moreover, hypoxia can prolong injury as a result of amplifying the early inflammatory response; this will increase the levels of oxygen radicals (Woo et al. 2007). In general terms, delayed surgical wound healing in diabetic patients with poor control is related to the enhanced inflammation, which disrupts the timing of new extracellular matrix synthesis: as a consequence, the quality of the restored collagen architecture is reduced; the inflammatory state is heightened in patients with poor hyperglycemic control (Shakya et al. 2015). As result of these physiological alterations caused by uncontrolled diabetes, the probability of SWCs at the harvest site and all other surgical sites is increased.

5.1.7 Peripheral Vascular Disease

Hemostasis, inflammation, proliferation and tissue remodeling are the normal regulated and integrated phases of wound healing (Henry et al. 2014). However, as identified above, oxygen plays a significant role in each phase of the healing process; patients with pre-existing peripheral vascular disease may suffer from delayed wound healing related to systematic localized hypoxia created by the anatomical alterations found in peripheral vascular disease (Armstrong et al. 2014). Sakakura et al. (2013) described the anatomical changes caused by peripheral vascular disease as beginning with intimal thickening of the peripheral vessels; this intimal thickening consists of increased smooth muscle cells and abnormal extracellular matrix deposits within the tissue. Thus, blood flow will be disrupted, leading to the creation of an ischemic environment.

In contrast to studies carried out Ku et al. (2005), Paletta et al. (2000), Abbaszadeh et al. (2008) and Sharma et al. (2009), peripheral vascular disease was not significantly associated with the incidence of SWCs post-harvesting in the present study (P = 0.869; OR = 0.744 [95% CI, 0.022 - 24.870]). This may be because of the strict policy followed at the KAMC: if a patient suffers from peripheral vascular disease or has a weak peripheral pulse, additional investigation is carried out, including segmental Doppler pressure and pulse volume, and if the Doppler ankle pressure is less than 50 mmHg, harvesting of the vein is avoided (Scher et al. 1986). However, in the worst case scenario, the policy in KAMC recommends the use of the endoscopic technique when patients are suffering from peripheral vascular disease; as shown in the raw data, all but one of the patients with peripheral vascular disease had their conduits harvested via EVH. One patient was not suitable for EVH, as his veins were anatomically superficial (Raja 2013).

5.1.8 Renal Function Failure

Insufficient renal function was the most significantly associated factor with the occurrence of SWCs in this current research (P = 0.0000008, OR = 0.043 [95% CI, 0.004 - 0.506]). Only Sharma et al. (2009) were in agreement with this finding; the other studies either did not investigate it (i.e. Abbaszadeh et al. 2008) or did not detect any association (i.e. Olsen et al. 2003).

To explain this significant association, it is essential to understand the role of protein in wound healing and the role of therapy for kidney disease in producing hypoproteinemia (low protein levels in the blood). During digestion, proteins are broken down into their component amino acids, which circulate through the blood and are taken up by tissues where they are required (Maroz and Simman 2013). The construction of new cells and tissues is essential for surgical wound healing, and amino acids are needed as building block components for the new proteins (Maroz and Simman 2013). Proper wound healing cannot be achieved without amino acids from the diet; thus, lack of protein specifically inhibits angiogenesis, synthesis of collagen and matrix and fibroblast proliferation.

Normally, healthy kidneys remove the waste products that result from ingested protein through millions of nephrons; these waste products are then removed from the body in the urine (Seth et al. 2013). However, in diseased kidneys, the ability to remove protein waste products and other toxic compounds is limited: therefore, these waste products start to build up in the blood circulation, meaning that kidney replacement therapy is required (Daugirdas et al. 2007). There are two common forms of kidney replacement therapy that are commonly used in clinical practice to treat patients with chronic renal insufficiency: haemodialysis (where the blood is pumped out of the body through tubes that connect to an artificial kidney machine) and peritoneal dialysis (where the dialysis fluid is infused through a catheter into the peritoneal cavity). Using either haemodialysis or peritoneal dialysis predisposes patients to significant protein loss (Daugirdas et al. 2007). Maroz and Simman (2013) reported the loss of 6–8 g of amino acids when using the haemodialysis procedure, while losing 8–20 g of protein per day when using the peritoneal cavity procedure. In summary, such a severe lack of protein caused by kidney replacement therapy will normally lead to hypoproteinemia, which will consequently cause SWCs (Daugirdas et al. 2007; Seth et al. 2013).

5.1.9 Cigarette Smoking

In general, the correlated association between cigarette smoking and the incidence of SWCs after surgery is well documented in the literature (Ahn et al. 2008; Sørensen et al. 2009). This may relate to the vasoconstrictive effects of nicotine, which causes decreased tissue blood flow and tissue ischemia; this vasoconstrictive effect is a result of the release of epinephrine due to sympathetic nervous activity stimulation by nicotine (Ahn et al. 2008). Nicotine also decreases fibrinolytic activity and increases the adhesiveness of platelets, leading to increased blood viscosity. Carbon monoxide also contributes to tissue hypoxia in smokers: it decreases the oxygenated haemoglobin fraction in the blood circulation, by binding to haemoglobin 200 times more aggressively than oxygen (Souza et al. 2004). However, cigarette smoking was not associated with SWCs in this research (P = 0.301; OR = 0.477 [95% CI, 0.121 - 1.879]), as shown in Table 4.3. This is consistent with all of the previously examined studies investigating risk factors for SWCs at the harvest site with the exception of Sharif-

Kashani (2016) who found a strong association between tobacco use and SWCs post harvesting (P= 0.010).

The disagreement in results in terms of the effect of smoking on SWC occurrence might be related to the use of nicotine replacement therapy in KAMC for patients who are smokers. Nicotine replacement therapy has been shown to attenuate inflammation and enhance proliferation, which is necessary to speed up surgical wound healing (Sørensen 2012).

5.1.10 The Intra-aortic balloon pump (IABP)

The IABP is an important physiological adjunct that increases myocardial oxygen perfusion and simultaneously improves cardiac output in order to increase coronary artery perfusion during diastole (Sharquie et al. 2012). Consistent with Palett et al. (2000) and Abbaszadeh et al. (2008), the use of an intra-aortic balloon pump (IABP) was significantly associated with SWCs in this research (P = 0.011; OR = 0.153 [95% CI, 0.036 - 0.650]), as shown in Table 4.3. Due to the location of the balloon tip in the aorta (about 1 cm distal to the origin of the left subclavian artery), a considerable risk of non- cardiac morbidity such as limb ischemia is highly expected (Sharquie et al. 2012). Siddiqi (2016) found the incidence of limb ischemia when using IABP to be around 20 to 30 percent. Therefore, this significant correlation of IABP with SWCs' incidence in this research might be a result of the effects of IABP on the peripheral circulation. However, investigating the effect of IABP on harvest site SWCs independently is difficult, as IABPs are used only in specific cases; these cases are usually confounded by other risk factors such as gender, diabetes and poor heart function.

5.1.11 Harvesting Techniques

Two harvesting techniques were investigated in this research: open and endoscopic techniques. Due to the nature of the open harvesting method (using one long continuous open skin incision until the required graft length is reached), it is considered to be a risk factor for the occurrence of SWCs at the harvest site, as identified above.

In agreement with studies conducted by Puskas et al. (1999) and Kalra et al. (2016), this research could not detect a significant association between the use of open harvesting and the occurrence of SWCs (P= 0.114). However, this is in disagreement with Allen et al. (1998), Blacka et al. (2002), Kiaii et al. (2002) and Andreasen et al. (2008), as they found the open harvesting method to be significantly associated with SWCs after graft harvesting. All of these studies that had inconsistent results with this research failed to provide sufficient information on who carried out the harvesting; thus, favouring one group over the other might be tainted by the effects of individuals' skills on the SWCs outcomes. Therefore, the inconsistency between this research and others on this point might be related to the influence of the surgical operators regardless of the harvesting techniques used.

5.2 Clinical Relevance of Findings

In order to provide a comprehensive discussion on the clinical relevance of these research finding and to provide relevant recommendations, the associated factors will be discussed separately under two subheadings: factors pertaining to surgical operators and other associated factors.

5.2.1 Surgical Operators

This research showed that the physicians' assistants are safe to practice in the substitution role within cardiac surgery at KAMC; this may have positive implications for the profession of physicians' assistants not only at the KAMC but even at Saudi national level. As previously stated, the non-medically qualified practitioners were introduced mainly to offset the shortage of doctors in cardiac surgery in KSA. However, this introduction was not efficient, as up to the current time, there is no clearly delineated nationally agreed curriculum, institutional policy or job profile. Gagliardi and Brouwers (2015) stated that the lack of working policy and procedures for healthcare practitioners will lead to unhealthy working conditions that may lead to poor quality working outcomes. Additionally, both McGlynn et al (2003) and Runciman et al (2012) argue that such a low quality service comes at a high financial cost. Thus, the drawing up of guidelines to determine the scope of practice of physicians' assistants in cardiac surgery is strongly recommended to facilitate the establishment of a more supportive practice environment that will enable physicians' assistants to optimize their expertise to provide a high quality of care services and maximize patient safety (Silva and Barbosa 2013); hopefully in a cost effective manner.

Although decision-making in health care is based on the value of research evidence, the incorporation of this evidence into decision-making remains somewhat inconsistent (Brazil et al. 2005). This may be because introducing any new changes in professionals' role in the healthcare setting is a quite difficult and challenging task (Al-Abri 2007). In this context, the change in the Kingdom of Saudi Arabia (KSA) would be more complex due to the variety of healthcare systems. The healthcare system in Saudi Arabia differs from that in the UK because there are more than seven national healthcare providers with different policies and procedures: these providers include Ministry of Health hospitals, University hospitals, National Guard hospitals, Armed Forces Hospitals, Security Force hospitals, King Faisal hospitals and private sector hospitals (Albejaidi 2010; Al-Hashem 2016).

Currently, there are two obvious challenges that need to be solved in order to achieve the effective introduction of physicians' assistants in a substitution role. The first is the healthcare organization, because all of the different healthcare systems in Saudi Arabia were developed for only two categories of healthcare practitioners (i.e. physicians or nurses). Second, as a consequence of the first challenge, physicians' assistants may struggle to find acceptance by other physicians and nurses in the same or different departments. Furthermore, other potential problems may arise as a result of proper implementation of physicians' assistants in a substitution role. These include the fear that some medical practitioners may experience erosion of skills if they rely on physicians' assistant (Jangland et al. 2014). In addition, it may indirectly affect physician-patient relations in the long term, as some medical practitioners feel that their presence will be restricted only to more difficult cases (Jangland et al. 2014). Such challenges are expected to exist when implementing the physician's assistant role in Saudi: therefore, to overcome these challenges, a long-term strategy to support this implementation in the health care system is highly recommended to ensure its success (Al-Abri 2007). This long-term strategy should involve at the outset a full explanation of the role of physicians' assistants, and their positive contribution to doctors, patients, nurses, administrators and others within healthcare settings. To ease planning for a long-term strategy to effectively implement this substitution role for physicians' assistants, theories on the implementation of change in healthcare must be used (Al-Abri 2007). This will provide a systemic framework to enable the understanding of the relationship between resources and their outputs or outcomes (Suter et al. 2009).

One of the aims in conducting a retrospective research is to generate a hypothesis that could be examined in a prospective manner (Matt and Matthew 2013). Therefore, additional prospective work of a non- inferiority design is recommended to investigate the hypothesis generated in this research: namely, physicians' assistants are providing comparable care to that provided by physicians when conducting saphenous vein or radial artery harvesting in CABG. An additional aspect of investigation involving the cost implications/effectiveness associated with surgical wound complications, in terms of length of stay, cost of consultation and additional therapy, will add value to future research. In addition, investigating the views of other health professionals such as doctors and nurses to identify and/or clarify the potential conflicts that might result from the substitution of physicians' assistants might be another vital point in future research. As physicians' assistants are employed by several heart centers in addition to the KAMC, conducting future research as multicenter trials will allow more comprehensive investigation of physicians' assistants in different settings in Saudi Arabia; this will also facilitate the investigation of the perceived value of the physician assistants' role to employers.

5.3 Strengths and Limitations

The current study distinguishes itself in the literature because it is the first study that sets out to illustrate an association between different types of surgical personnel and surgical wound complications after graft harvesting. In addition, by investigating the effects of physicians' assistants, this research has provided valued information that highlights the hidden positive contributions of physician' assistants in cardiac surgery at King Abdullah Medical City for the first time for this profession in the Kingdom of Saudi Arabia. Despite 41 years of experience of the non-medical practitioners' substitution role in cardiac surgery, this is the first research conducted in this field. To date, no studies have been conducted to explore the prevalence of SWCs post conduit harvest or to investigate contributing risk factors within the Saudi context. This is in part is because of the lack of national registries (Cevallos et al. 2016). Only a single published abstract, by Arifi et al. (2016), has identified a root-cause analysis of the increased rates of SWCs in Saudi CABG patients. However, very limited detail is provided and thus this abstract is of limited value.

Although the validity of this research was ensured by double entry of the data by independent data collectors, as previously stated, this research is limited by the possibility that some data might have been documented inaccurately in patients' records. In addition, some records might have been missed due to the short time available for data collection. Furthermore, as the KAMC is a referral hospital that covers the whole of the south western region of the Kingdom of Saudi Arabia, it is possible that some patients acquired SWCs at the harvest site after discharge but did not seek care at the KAMC; this could introduce bias in the collected information, and due to the nature of this research (retrospective chart review), it is not possible to be certain about such cases. Therefore in order to capture a fuller picture of the reality of SWCs in the target population, a prospective study with an appropriate follow up period should be considered. Finally, this research was carried out by a novice researcher: therefore, it is possible that some relevant studies of additional factors associated with SWCs at the harvest site were missed while reviewing the literature; this could potentially bias the findings by omitting other associated factors.

6.Conclusion

Coronary artery bypass graft (CABG) is a surgical intervention that is used to treat complex coronary artery disease (Khan et al. 2010). To perform this surgery, the long saphenous veins from the legs and/or the radial artery from the arms are harvested in order to use them as bypass grafts (Cao et al. 2013). However, one of the most common complications after CABG is the occurrence of surgical wound complications (SWCs) at the harvest site, which can limit the benefits of surgical intervention because of its association with an increase in morbidity and mortality, ranging from superficial skin infection associated with wound discharge to life-threatening conditions such as severe sepsis (Anderson and Kaye 2009; Kaye et al. 2008). In some cases, SWCs post conduit harvest requires additional surgical intervention such as debridement, with possible lower extremity revascularization or loss of the limb in the worst case scenario (Turtiainen and Hakala 2013). Other than the impact of SWCs on patients' postoperative recovery, they can also have a psychological effect on patients in the form of depression or anxiety due to the possibility of prolonged recovery or long-lasting disability (Pinto et al. 2015). Therefore, the occurrence of SWCs at the harvest site is a genuine issue that contributes to significant morbidities and presents a substantial burden on both patients and healthcare systems (Si et al. 2014).

There are many factors that can influence the incidence of SWCs at the harvest site: these include endogenous factors such as demographics and comorbidities and exogenous factors such as the use of invasive devices and the level of the surgical operators' surgical skills. As there is a significant shortage of medical staff in the field of cardiac surgery in the Kingdom of Saudi Arabia, the concept of non-medically qualified practitioners taking a substitution role within cardiac surgery has been introduced. Such variation in qualifications between medical and non-medical practitioners is stated to be a potential exogenous influencing factor for the incidence of SWCs at the harvest site; however, no previous study has been conducted to investigate this factor. Thus, this research was conducted to identify whether or not there was an association between the involvements of physicians and physician' assistants and the occurrence of SWCs at the harvest site in CABG. Illustrating such an association would aim to provide evidence on whether or not the new substitution role of physicians' assistants within cardiac surgery at KAMC is safe.

A retrospective chart review method with a cohort design was chosen to meet the aim of this research. Data collection activities took place at the medical records department in the KAMC thorough three data abstractors, including the researcher. Required data were recorded in a spread sheet and categorized according to an agreed protocol that was created especially for this study. Collected data were electronically imported to SPSS in order to analyse them to provide an answer for the investigated enquiry.

This research resulted in a confirmation of the stated null hypothesis, as the involvement of physicians' assistants was not significantly associated with the incidence of SWCs at harvest site. Such a result provides a definitive answer to this research question: this answer is that certified physicians' assistants at KAMC did not influence the occurrence of SWCs at harvest sites when they are utilised to harvest the saphenous vein or the radial artery in CABG.

As it clearly appears in the discussion chapter, there are areas of agreement and conflict between this study's results and those of previous studies appraised in the literature chapter. Thus, it is important to note that this study was conducted only to explore the factors associated with SWCs and not the causative factors of SWCs, which are beyond the scope of this research. It would thus be strongly recommended to conduct further research with a case-control design to investigate the actual causative factors for SWCs at harvest sites (Mann 2003). Finally, this research has confirmed whilst it is safe for physicians' assistants to carry out saphenous vein or radial artery harvest in CABG at KAMC, further multicentre prospective research is recommended to investigate the contributory value of physicians' assistants in the Kingdom of Saudi Arabia.

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