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A randomised controlled trial of mini incision or conventional incision for saphenous vein harvesting in patients undergoing myocardial revascularization

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HIGHLIGHTS

- Benefits of with mini-incision surgery for saphenous vein stripping have been demonstrated.
- We present a technique without aid of special material.
- The number of postoperative complications was smaller and evolved faster.
- With this technique there is no increase in hospital costs and nor of the team's curve learning.

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ABSTRACT

Objective: Compare the evolution regarding the complications concerning two types of incision (conventional × mini-incision), for saphenectomy in patients that go under myocardial revascularization or otherwise known as coronary artery bypass surgery.
Methods: In January 2012 to August 2013, 66 patients were prospectively selected for coronary artery bypass with cardiopulmonary bypass surgery. These were divided into two groups: Conventional and Mini-Incision, with 33 patients in each group chosen in a random fashion and with knowledge of which technique to be used being presented only at the start of the surgery. In the conventional group, the patients received an incision to the lower member of 7–10 cm. The patients in the Mini-Incision group received an incision to the lower member of 3–4 cm, both performed without the use of any special material.
Results: The groups were similar in terms of clinical data and in the preoperative period. Males made up a greater part of the group with 63.7% and 81.9% in groups C and M, respectively. Among the complications analysed, edema ($p = 0.011$), hematoma ($p = 0.020$), dehiscence ($p = 0.012$) and infection ($p = 0.012$), were significantly greater in group C when compared to group M. When the matter comes to the variable in relation to the risk of Surgical Site Infections (SSI), no difference was found between the groups.
Conclusion: Coronary artery bypass surgery with mini-incision for saphenectomy, demonstrated a lower rate for preoperative complications when compared to saphenectomy under conventional incision procedures.

1. Introduction

Cardiovascular diseases (CVD) are among the primary causes of death worldwide: more people die annually from cardiovascular related diseases than any other cause [1].

Coronary Artery Disease (CAD) occurs in greater frequency through the obstruction of the coronary artery by atheromatous plaques and usually affects individuals with stenosis of the epicardial arteries [2].

Surgical Coronary artery bypass, is generally indicated for those

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patients where clinical treatment is unable to control angina pectoris or those that have an elevated level of arterial obstruction, which thus elevates their risk to a life threatening one. In general, these are patients that present diffuse coronary lesions, with involvement of more than one coronary territory along with the involvement of vital arteries, such as the left main coronary artery and the left anterior descending branch [3].

Although the use of arterial conduits for grafts in coronary artery bypass surgery has grown over recent years, the saphenectomy technique used for obtaining the venous graft during surgical intervention, is still one of the most commonly performed procedures worldwide. Usually, the dissection of the great saphenous vein is performed through the open surgery technique with single or staggered incisions. Complications related to the surgical technique, occur in 30% of the patients submitted to a saphenectomy. Hematoma, seroma, suture dehiscence, necrosis around the edges of the incisions or infections, increase hospital stay periods and delay patient rehabilitation. DeLaria et al. revealed an increase of 12 days in hospital stay due to complications at the saphenectomy site. This incurred an increase of US$ 9900 per patient in hospital costs linked to these patients [4].

Complications of a lesser degree that lead to cicatrisation difficulties can affect up to 44% of patients. Infections associated with the lower members is around 99% more common than on the sternal incision, this in most cases represents the main grievance of postoperative patients [5].

New saphenectomy techniques have been proposed with the aim of decreasing postoperative complications. Chukwuemeka and John proposed initiating the leg incision 5 cm above the medial malleolus and extend it proximally, avoiding more distal areas. Saphenectomy performed with small staggered incisions was one of the first techniques to be proposed. This is basically performed through the use of minimally applied intercalated incisions along the saphenous vein, creating an interposition of skin “islands”. Tevaearai et al. report speedier recovery from surgery for patients where the mini-incision technique was used, which through avoiding large skin flaps and promoting a lesser degree of lesions in lymphatic vessels, attains an improved aesthetic result [4].

Minimally invasive techniques performed by means of endoscopic and non-endoscopic instruments, with the intention of further decreasing surgical incisions and improve the visualization of the saphenous vein have been advocated since 1996. This methodology brings about a reduction in trauma to fatty tissues, decrease in lesions to skin nourishing vessels and postoperative infections. Pagni et al. showed a 60% reduction in the risk of infection in saphenectomy patients through the use of video-assisted techniques [4].

Initial results have demonstrated that less invasive procedures do provide effective surgical treatment, along with accelerate patient recuperation, decrease hospital stay time and reduce the overall cost. This path of minimally invasive dissection of the saphenous vein has attracted the attention of various researchers. Preliminary studies with the use of video-endoscopy, has demonstrated that limited surgical incisions are capable of reducing postoperative mortality. However, video-endoscopy surgeries require the acquisition of new abilities and equipment. The initial period for the learning curve can hamper results as well as the inherent necessity of investment for the acquisition of these materials may become a prohibitive factor for many institutions [5].

Aimed at reaching the benefits of the minimally invasive approach, however, without the use of video-endoscopy, brought about the study for alternative methods through which the saphenous vein could be obtained. Through mini-incisions and the aid of a long and narrow blade retractor, one is able to dissect the required segment of vein. In 1997, Dias et al. presented an initial series of 8 patients to which similar techniques were employed. Through mini-incisions to the skin they were able to dry out a satisfactory length of vein, with a low rate of complications to the wound [5].

The improvement to those conditions that inhibit the recuperation of operated patients, thus optimizing their recuperation and avoiding possible postoperative complications, has guided researchers in the search for new techniques as well as their improvement. The final goal being therefore, that surgical intervention reaches a successful conclusion, which reflects upon the life quality of the patient.

The objective behind this study was to compare two types of incision for saphenectomy: conventional incision (7 cm to 10 cm) and mini-incision (3 cm to 4 cm) without the use of special materials in regards to the occurrence of complications to the saphenectomy surgical site, such as pain, edema, hematoma, dehiscence, necrosis, infection and seroma.

2. Method

Based on a randomized clinical trial of the types and evolution of saphenectomy incisions in patients that are submitted to coronary artery bypass surgery.

This study was designed to evaluate 66 patients that were submitted to cardio coronary artery bypass surgery, with prospective cardiopulmonary bypass. This number of patients was calculated taking into consideration a 30% complication rate for saphenectomy surgeries and 10% for minimally invasive surgeries and a power test of 90% and confidence at 95%.

The retrieved data were submitted to statistical treatment where the qualitative variables, such as pain, edema, hematoma, dehiscence, necrosis, infection and seroma, were analysed through the use of the Binomial Test between two portions.

The analysis of the quantitative variables was performed through use of the Shapiro Wilk test in order to check if the data possess normal distribution; those that had normal distribution the student's t-test was used for two independent samples, those which did not possess normal distribution were submitted to the Mann Whitney test.

Selected for the study was every patient registered at the CHUFU who was older than 18 and that had been submitted to only coronary artery bypass surgery, with the removal of the great saphenous vein through one of the proposed incisions. Patients excluded from this selection were those that had undergone other surgical methods besides coronary artery bypass and saphenectomy, such as: valve replacement, aneurysm repair, carotid endarterectomy; revascularization without the use of cardiopulmonary bypass (CPB) among others, also prolonged cardiopulmonary bypass (CPB) (>than 120 min).

The surgeries were performed during the period from January 2012 to August 2013. For randomization purposes, it was necessary that the patients, parents or guardians agreed and signed a patient consent form (PCF), after a full clarification had been given by a member of the team.

Once these criteria had been appropriately completed, the patient was selected and invited to participate in the study. After their acceptance, these patients were randomly placed into two groups: Group C (conventional incision) and Group M (mini-incision).

The random selection was performed through the medical record number prior to the beginning of the study and knowledge on the part of the surgeon as to the selected group was given only at the start of surgery. The patient therefore, had no idea of the saphenectomy technique that would be executed on the lower member.

In the conventional group, the incision performed on the lower

member was 7 to 10 cm. In the mini-incision group the incision was from 3 to 4 cm, with a comparative study of the evolution of the postoperative saphenectomy surgical site being carried out.

In order to perform the incisions, the lower member was positioned with partial thigh abduction, external rotation and light hip flexion, obtained with the aid of sponge cushions placed under the patient's thigh and knee. For the dissection procedure curved Metzenbaum scissors and digital manoeuvres were used with the aid of Farabeuf and Weitlaner retractors, scalpel number 24 and Debakey dissection forceps. The control of hemostasis was performed through use of non-absorbable poly-filament Polycot 4-0, electrocautery coagulation at 30 W and metal clip clamp. To approach the subcutaneous tissue absorbable monofilament wire Caprofyl 0 (poliglecaprone 25) was used and for suturing the skin, absorbable monofilament wire Monocryl 4-0 (poliglecaprone 25) was used.

The first incision was performed lengthwise, along the course of the great saphenous vein, 10 cm below the inguinal fold. The subcutaneous and adipose tissue were dissected and the vein identified. Incisions were staggered with interposition flaps of intact skin along the saphenous vein as shown in Fig. 1.

The size of the incision differentiated group C from group M, in that group C an incision of 7 to 10 cm was made and in group M an incision of 3 to 4 cm.

To carry out an evaluation of pain, the authors used the numeric scale according to the Regulatory Circular Nº 09/DGCG of 14/06/2003 from the Ministry of Health in accordance with the World Health Organization. In relation to edema, hematoma, dehiscence, necrosis and seroma, the authors evaluated to which degree these complications were present. The evaluation of infection was performed in accordance with the defining classification and criteria for surgical infection from the National Health Surveillance Agency of the Ministry of Health. Those being superficial and deep incisional and organ or cavity, then this variable is stratified according to the Surgical Site Infection Risk Score (SSIRS). This risk evaluation method from SSI, considers the potential for contamination from surgeries, along with the patient's health state and surgery duration, these in turn, adopt the methodology from the NNISS (National Nosocomial Infection Surveillance System from the Centre for Disease Control and Prevention – EUA).

The authors evaluated the variables that can interfere with the homogeneity of sampling, such as: sampling features, risk factors, length of stay, drug therapy and invasive procedures carried out to see if there was a significant difference between the groups.

In regards to antibiotic prophylaxis, the authors carried out a three stage division: pre-surgical Antibiotic (the authors considered all those administered and for any motive for the 48 h prior to surgical procedure), prophylaxis Antibiotic (that administered in accordance with the routine for cardio surgery during aesthetic induction up to 48 h postoperative) and postoperative Antibiotic (that administered after 48 h of postoperative until the patient's discharge from the hospital unit).

This work was developed at the Hospital de Clínicas da Universidade Federal de Uberlândia (HC-UFU) (Clinical Hospital of the Federal University of Uberlândia (CH-UFU)) and at the Cardiac Surgery Clinic of the selfsame hospital, together with the cardio surgical team. The patient was monitored daily in the intensive care unit (ICU) or in the Internal Medicine ward, with data collected during the first 36, 72, 96 h and on the 7th (seventh) day of postoperative. Clinical monitoring was carried out by the cardiac surgery service from CH-UFU, during 30 days of postoperative.

This study was conducted upon the submission of its research protocol to the Ethics Committee of the Federal University of Uberlândia and the Clinical Board of the Clinical Hospital of the Federal University of Uberlândia for analysis, and was thus approved under the protocol 077/12 325/11.

There is no conflict of interest on the part of any of the researchers involved in this research project.

3. Results

Sixty eight cases met the inclusion criteria. These were distributed randomly into two groups of 33 patients all submitted for saphenectomy: by conventional incision (group C) and by mini-incision (group M).

The clinical features of the pre-operative were similar in both groups. These data are demonstrated in Table 1.

Every patient was submitted to coronary artery bypass surgery, however, two patients from the conventional group, and three patients from the mini-incision group, also underwent a Left ventricular aneurysm (LVA), $p = 0.6418$.

Regarding the length of stay the authors retrieved results as presented in Table 2.

One observes that in relation to the average for length of stay in the postoperative and in the average for total length of stay (pre-operative + postoperative), there was a significant statistical difference, with a P of 0.04 and 0.03 respectively. If one considers only the average for length of stay for pre-operative there was no significant difference ($p = 0.49$).

When the performed pre-operative invasive procedures were analysed from the patients of both groups, no significant difference was found between the groups ($p = 1.00$).

Regarding the medication used, there was no significant difference between the two groups, which allows one to draw the conclusion that the two groups were similar in the therapy used.

On the topic of antibiotic therapy pre-operative ($p = 1.00$),

Fig. 1. Incision technique for saphenous vein harvesting.

Table 1
Characteristics of the analysed samples during the pre-operative period.

Pre-operative Variable	Conventional N = 33	Mini-incision N = 33	*P*
Age	61.85 ± 7,94	65.30 ± 8,84	0.10
BMI	26.82 ± 3,95	25.80 ± 3,66	0.20
Sex			
Masculine	21 (63.63%)	27 (81.81%)	0.09
Feminine	12 (36.37%)	6 (18.19%)	
Hypertension	30 (90%)	30 (90%)	1.00
Diabetes Mellitus	19 (57%)	15 (45%)	0.32
Dyslipidaemia	13 (39%)	11 (33%)	0.60
Smoker	12 (36%)	8 (24%)	0.28
Ex-Smoker	11 (33%)	15 (45%)	0.31
Early AMI	8 (24%)	7 (21%)	0.76
Obesity	6 (18%)	4 (12%)	0.49
Alcoholic/Ex-alcoholic*	3 (9%)	2 (6%)	0.64
Kidney Failure	3 (9%)	2 (6%)	0.64

BMI – Body Mass Index, AMI – Acute Myocardial Infarction.
* At least one year without alcohol.

Table 4
Saphenectomy infection according to the SSIRS.

SSIRS	Conventional	Mini-incision	*P*
	Infection (N/%)	Infection (N/%)	
0	2 (3%)	0 (0%)	0.104
1	4 (6%)	0 (0%)	0.051
2	2 (3%)	1 (1.5%)	0.310
3	0 (0%)	0 (0%)	–

N (%) = number of patients expressed in absolute value and percentage, SSIRS - Surgical Site Infection Risk Score.

4. Discussion

The predominance of male patients submitted to coronary artery bypass surgery with saphenectomy, are found to be similar to those studies performed in other areas, which present (68.55%), (54.3%) and (80.3%) of coronary artery disease in males, respectively [6–8].

Table 2
Length of stay in days for the Conventional and Mini-incision group.

	Conventional				Mini-incision				
Days	Min (d)	Max (d)	Average	SD	Min (d)	Max (d)	Average	SD	*P*
Length of Stay Pre-operative	2	60	20.58	15.43	2	40	16.36	8.92	0.49
Length of stay Postoperative	6	87	22.18	18.10	6	44	15.24	12.53	**0.04**
Length of Stay Total (Pre+Post)	16	114	42.76	23.16	12	67	31.67	16.61	**0.03**

Statistically significant.
d – Days, SD – Standard Deviation.

prophylactic (p = 0.31) and postoperative (p = 0.28), all groups were homogenous without any statistical difference between them.

On the subject of the analysis for complications from surgical incision, during the postoperative period the results shown in Table 3 were observed.

Among those complications associated with the surgical site, edema (p = 0.011), hematoma (p = 0.020), dehiscence (p = 0.012) and infection (p = 0.012), were significantly higher in the Conventional group compared to the Mini-incision. There was 7 times more dehiscence and infection, 10 times more edema and 2 times more necrosis in the conventional group.

In order to carry out the assessment for the rate of infection in the composition of the two groups (C and M), the authors used the Surgical Site Infection Risk Score (SSIRS), in accordance with the methodology laid out by the NNISS (National Nosocomial Infection Surveillance System from the Centre for Disease Control and Prevention- EUA), and can be seen in Table 4.

When the variable for infection is stratified according to the risk of infection, one notes that there was no difference between the groups.

Table 3
Complication at the saphenectomy site of revascularized patients submitted to both conventional and mini-incision.

Complications	Conventional N/%	Mini-incision N/%	*P*
Pain	13 (39.5%)	9 (27%)	0.29
Edema	18 (54.5%)	8 (24%)	**0.01**
Hematoma	26 (79%)	17 (51.5%)	**0.02**
Dehiscence	8 (24%)	1 (3%)	**0.01**
Necrosis	2 (6%)	0 (0%)	0.15
Infection	8 (24%)	1 (3%)	**0.01**
Seroma	2 (6%)	1 (3%)	0.55

Statistically significant.
N (%) = number of patients expressed in absolute value and percentage.

The results retrieved as to the age range were close to those encountered in a study carried out in the state of São Paulo, Brazil in 2007, where an average age range of 60 was obtained and an SD ± 8, in group C the average was 61.8 ± 7.94 and in group M 65.3 ± 8.84 [8].

Regarding the average for the BMI of 26.82 ± 3.95 in C and an average of 25.80 ± 3.66 in group M, one notes that both show similarity to those averages found in the state of São Paulo, Brazil in 2007, which presented an average BMI of 26 kg/m2 and SD ± 3 [9].

In this study, the authors sub-divided the length of stay into: pre-operative admission (from the initial admission to the surgery date), postoperative (from the surgery until patient discharge) and total admission time (admission pre + postoperative).

During the pre-operative admission period the authors' results differ to those from other published works. According to a study realized by Fernandes et al. [10], in a cardiology reference hospital, the hospital stay period found for cardio surgeries is on average around 6.6 days in pre-operative, with an average of 5.4 ± 5.9 days in the ICU.

It is believed that the increase in number of days for pre-operative admission found in this study, is due to the characteristics of the hospital where the study was carried out, which in fact is a general hospital with a general ICU without a specific ward for cardio surgery. This hospital is in fact a highly complex unit, fully integrated onto the SUS network, which serves a population of more than two million inhabitants, covering 86 municipalities with 520 beds but with only 30 ICU beds. Due to these characteristics, the wait time for elective surgeries is high, mainly due to the need for an available ICU bed in order to carry out cardio surgery.

Concerning postoperative admission, group C presented an average of 22.18 ± 18.10 days and in group M an average of

15.24 ± 12.53, with a significant difference between the groups ($p = 0.04$).

When the total admission time was evaluated, a contrast was noted in relation to other referenced works. For group C the average was 42.76 ± 23.16 days and for group M the average was 31.67 ± 16.61 days.

According to a study carried out by Laizo et al., the ICU admission period was from 1 to 21 days, with an average of 4.16 ± 3.76 days. However, in another study, the length of hospital stay was 14.5 days on average, with a standard deviation of 12.3 days. The average Intensive Care Unit (ICU) admission period, was 3.8 days, with a standard deviation of 4.0 days. Moreover, for Mesquita et al., the admission period was 11 ± 9 days [11–14].

The high rate for length of stay in this study is affected by the high pre-operative admission period experienced in this work's hospital of reference, in addition to its already high postoperative admission. When the authors carried out a statistical analysis, a significant difference in postoperative surgery was noted, with group C attaining the highest number of admission days. This prolonged admission has been associated with greater complications in group C, due to the significant statistical difference between the groups.

It is well known that cardio surgery complications can be attributed to pre-existing diseases. A study carried out in 2010 pointed to the main pathologies that can contribute towards greater postoperative complications in coronary artery bypass surgery, previous pulmonary diseases COPD, asthma, smoking, old age, bad nutrition, obesity, diabetes [15].

When it comes to the risk factors for postoperative complications, in this study it was noted that 30% of patients mentioned smoking, 90% hypertension, 51% diabetes mellitus, 36% dyslipidaemia and 22.5% acute myocardial infarction. The data retrieved differs from the results found in a study carried out in São José do Rio Preto, São Paulo, Brazil in 2013, in which 24.1% of patients were smokers, 74% hypertensive, 27% diabetic, 64% dyslipidaemia and 67.2% present previous history of acute myocardial infarction [16].

In a study carried out by Dantas [17], a report of 76% surgical site complications was observed. In the present study, edema, hematoma, dehiscence and infection were significantly higher in group C. it is suggested that recuperation and healing of the surgical wound progressed more quickly with the minimally invasive technique, decreasing admission time and hospital costs.

A variety of antibiotics are used to perform surgical prophylaxis. According to the Treatment Guidelines from the Medical Letter, cefazolin, cefuroxime or vancomycin should be used in cardio surgery as antibiotic prophylaxis [18].

A study carried out in 2011 in Rio de Janeiro, evaluated the prevention of surgical site infection, through the use of antibiotic prophylaxis in patients submitted to elective cardio surgery, the study also demonstrated that the number of hospital admission days after cardio surgery was reduced, due to the decrease in hospital infection [19]. This study confirms the predominant use of cefazolin in surgical prophylaxis, this finding is in line with current literature, which largely indicates this medication for surgeries outside the distal intestinal tract [20].

In this study, the SSI rate was similar to that identified in the literature, which varied between 0.2% and 5.6% [21–23].

FREITAS [24] conveys that indicators based on only the number of infections and performed procedures are limited in specification, since on one hand they do not amply express the degree of exposure to potential risk factors as well as being susceptible to other influences and not the quality of services. The reporting of SSI rates stratified in accordance with the potential risk factors associated with infection is, therefore, highly recommended.

When the infection variable is stratified in accordance with the NNIS, through the Surgical Site Infection Risk Score (SSIRS), one notes that no discernible difference is found between the groups.

Stratification in a composite risk score, which considers the patient's general physical condition, a classification of wound contamination and length of procedure, produces comparisons with greater comprehension than in the grouping of all the SSI numerators [24].

5. Conclusion

Mini-incision for saphenectomy in coronary artery bypass surgery, showed a lower number of complications when compared to conventional incision.

The postoperative hospital admission time was significantly less in those individuals that underwent mini-incision surgery, suggesting better outcomes in recovery and healing of the operatory wound.

Through an evaluation of infection rates, the highest occurrence was observed in the conventional incision group. Through the stratification of this variable, in accordance with NNIS methodology, which considers the patient's general condition, surgery time and the classification of contamination potential, one notes there were no differences between the groups.

Ethical approval

This study was conducted upon the submission of its research protocol to the Ethics Committee of the Federal University of Uberlândia and the Clinical Board of the Clinical Hospital of the Federal University of Uberlândia for analysis, and was thus approved under the protocol 077/12 325/11.

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Author contribution

Kleber Gontijo de Deus: Study design, data collection, analysis, writing.

Augusto Diogo Filho: Study design, data collection, analysis, writing.

Paulo Cesar Santos: Study design, data collection, analysis, writing.

Conflicts of interest

There is no conflict of interest.

Guarantor

Kleber Gontijo de Deus, Augusto Diogo Filho, Paulo Cesar Santos.

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