

# CLINICAL-DEMOGRAPHIC ASPECTS OF PATIENTS TO CARDIAC SURGERY **ELECTIVE**

## ASPECTOS CLÍNICO-DEMOGRÁFICOS DE PACIENTES SUBMETIDOS À CIRURGIA CARDÍACA **ELETIVA**

ASPECTOS CLÍNICOS DEMOGRÁFICOS DE PACIENTES SOMETIDOS A LA CIRUGIA CARDÍACA **ELECTIVA** 

Fernanda Dallazen<sup>1</sup>, Pollyana Windmöller<sup>2</sup>, Evelise Moares Berlezi<sup>3</sup>, Eliane Roseli Winkelmann<sup>4</sup>

#### **ABSTRACT**

Objective: to characterize the clinical and demographic characteristics of patients undergoing cardiac surgery. Method: cross-sectional study with 219 patients undergoing cardiac surgery, and 140 surgeries of coronary artery bypass graft (CABG) and 79 surgical aortic valve replacement, mitral or pulmonary (TValvar) between July 2010 and December 2014. Data collection was from the analysis of medical records. Results: the most prevalent cardiovascular risk factors were hypertension, smoking in the past and family history of CAD, being more significant in CABG procedure. Patients are in pre-obesity with high coronary risk. The mean duration of surgery was 3 and a half hours and the length of hospital stay of 6 days. The most frequent postoperative complications were respiratory and hemodynamic, focusing on CABG. Conclusion: it was possible to characterize the clinical and demographic characteristics of patients undergoing elective surgery. Descriptors: Thoracic Surgery; Health Profile; Epidemiology; Physiotherapy.

#### **RESUMO**

Objetivo: caracterizar os aspectos clínico-demográficos de pacientes submetidos à cirurgia cardíaca. Método: estudo transversal, com 219 pacientes submetidos à cirurgia cardíaca, sendo 140 cirurgias de revascularização do miocárdio (CRM) e 79 cirurgias de troca valvar aórtica, mitral ou pulmonar (TValvar) entre julho de 2010 e dezembro de 2014. A coleta de dados foi realizada a partir da análise de prontuários. Resultados: os fatores de risco cardiovasculares mais prevalentes foram HAS, tabagismo no passado e histórico familiar de DAC, sendo mais significativo no procedimento de CRM. Os pacientes se encontram em pré-obesidade com elevado risco coronariano. A duração média da cirurgia foi de 3 horas e meia e o tempo de internação hospitalar de 6 dias. As complicações pós-operatórias mais frequentes foram respiratórias e hemodinâmicas, com maior incidência na CRM. Conclusão: foi possível caracterizar os aspectos clínico-demográficos dos pacientes submetidos à cirurgia eletiva. Descritores: Cirurgia Torácica; Perfil de Saúde; Epidemiologia; Fisioterapia.

Objetivo: caracterizar los aspectos clínico-demográficos de pacientes sometidos a cirugía cardíaca. Método: estudio transversal, con 219 pacientes sometidos a la cirugía cardíaca, siendo 140 cirugías de revascularización del miocardio (CRM) y 79 cirugías de cambio de la válvula aórtica, mitral o pulmonar (TValvar) entre julio de 2010 y diciembre de 2014. La recolección de datos fue realizada a partir del análisis de prontuarios. Resultados: los factores de riesgo cardiovasculares más prevalentes fueron HAS, tabaquismo en el pasado e histórico familiar de DAC, siendo más significativo en el procedimiento de CRM. Los pacientes se encuentran en pre-obesidad con elevado riesgo coronario. La duración media de la cirugía fue de 3 horas y media y el tiempo de internación hospitalario de 6 días. Las complicaciones post-operatorias más frecuentes fueron respiratorias y hemodinámicas, con mayor incidencia en la CRM. Conclusión: fue posible caracterizar los aspectos clínico-demográficos de los pacientes sometidos a cirugía electiva. Descriptors: Cirugía Torácica; Perfil de Salud; Epidemiología; Fisioterapia.

¹Physiotherapist, Master degree student of the Graduate Program in Gerontology of the Federal University of Santa Maria/UFSM. Santa Maria (RS), Brazil. E-mail: <a href="mailto:fer\_dallazen@hotmail.com">fer\_dallazen@hotmail.com</a>; ²Physiotherapist, Specialist Professor in Hospital Physiotherapy, Department of Life Sciences/DCVida - UNIJUI. Ijui (RS), Brazil. E-mail: <a href="mailto:pollyana.w@unijui.edu.br">pollyana.w@unijui.edu.br</a>; ³Physiotherapist, Professor in Gerontology, Graduate Program in Integral Attention in Health/UNIJUI, Graduate Program in Gerontology/UFSM). Santa Maria (RS), Brazil. E-mail: br; <sup>4</sup>Physiotherapist, Ph.D. in Health Sciences: Cardiology and Cardiovascular Sciences at the Federal University of Rio Grande do Sul (UFRGS), Graduate Program in Integral Attention in Health/UNIJUI. Ijui (RS), Brasil. E-mail: elianew@unijui.edu.br

INTRODUCTION

With the demographic transition occurring in recent decades, the aging population is a phenomenon that has been featured in Brazil and worldwide. Estimates point to the possibility that in the next 20 years in Brazil, the number of elderly exceeds 30 million people, representing almost 13% of the

population,<sup>1</sup> placing us as the sixth elderly population in the world in 2015. Among the most frequent causes of death in the elderly, there are the heart disease, cancer and cerebrovascular disease.<sup>2</sup>

Considering these data and according to several studies demonstrating the efficacy, the improve of quality of life and increase survival by coronary artery bypass graft (CABG),<sup>3</sup> an increase in the indication of the treatment surgical coronary artery disease and degenerative valve disease in the elderly.<sup>4</sup>

Over the last years, the treatment of ischemic heart disease has undergone significant changes, with implications for the natural history of the disease and surgical indication. The CABG is a therapeutic procedure used in this treatment, in which it has great importance since the decade of the 60s. As the first surgery for correction of valve disease (TValvar) were performed in 1952, using prostheses in patients with aortic insufficiency. 9-10

Several national studies have evaluated the epidemiology of patients undergoing CABG sought to know the profile (risk factors and comorbidities) and clinical outcome (complications) in patients undergoing CABG from July 2009 to July 2010 in a State Hospital of São Paulo, 11 as well as in a hospital in the state of Rio de Janeiro, between August 2004 and June 2009 analyzed the epidemiological aspects of CABG. 12

There are few studies that bring the profile or epidemiological aspects of patients undergoing surgery for TValvar. Valvulopathies are around 12% to 15% of outpatient visits, and incidence of the valvular disease is approximately 220 patients/year in the state of Rio Grande do Sul. Still, Brazilian prevalence data and epidemiological studies in population are scarce and controversy.

In this context, the clinical and demographic characteristics of patients undergoing cardiac surgery in the interior of Rio Grande do Sul (RS) are little known, although it has heart surgery services of high complexity. Thus, this study is justified with the objective to characterize the clinical and

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demographic characteristics of patients undergoing elective cardiac surgery.

## **METHOD**

Cross-sectional, retrospective and analytical study approved by the Ethics and Research of the Regional University of the Northwest of Rio Grande do Sul Committee - UNIJUÍ (Number 1039.457/2015) and developed by the Guidelines and Standards for Research Involving Human Beings according to the National Council of Health (CNS) (number 196/1996).

There were 219 patients included in the study undergoing elective cardiac surgery of CABG or TValvar from July 2010 to December 2014 in a General Hospital Size IV of the Northwest region of Rio Grande do Sul, Brazil.

For this study, a retrospective analysis of medical records was performed using a form specifically designed for this purpose. Identification variables of individuals were age, gender, city and occupation: factors: high blood cardiovascular risk pressure (HBP), dyslipidemia, diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), smoking (the past and present), sedentary lifestyle, stress, previous events such as acute myocardial infarction artery disease family Anthropometric variables were: height, waist circumference (WC), body mass index (BMI) and the conicity index (CI). measurements of weight, height and waist circumference were used to determine the CI using the mathematical equation according to Valdez (1991). 15 The chosen cutoff points according to the study of Pitanga and Lessa were greater or equal to 1.25 for men and greater than or equal to 1.18 for women.<sup>16</sup>

The intra-operatively variables analyzed were a time of surgery, cardiopulmonary bypass (CPB) time, clamping time of the aorta, recovery rate and type of drain used. In the postoperatively, the variables were time on mechanical ventilation (MV), hospitalization in the coronary care unit (ICCU), hospital stay and total hospitalization.

To facilitate the analysis, the complications of OPs were divided into 7 groups, which were neurologic complications (psychomotor agitation, mental confusion and syncope), cardiovascular complications (hypotension, tachycardia, and cardiogenic respiratory complications (hemoptysis, pleural effusion, pleural fistula, pneumothorax, reintubation); atelectasis and complications (bleeding, and ischemia); hemodynamic complications (bleeding and thrombocytopenia); digestive complications

(nausea and vomiting); and renal complications (aerodynamics and oliguria evaluation).

For data analysis, the Statistical Package for Social Sciences - SPSS (version 18.0, Chicago, Illinois) was used. The Kolmogorov-Smirnov test was used to check the normality of the variables. The results were presented in absolute and relative frequencies, mean and standard deviation. The Mann-Whitney test was used to compare two independent groups with a normal distribution. Pearson's chi-square test was used to compare categorical variables. It was considered significant one p  $\leq$  0.05.

#### **RESULTS**

The study consists of 219 patients who underwent cardiac surgery between 2010 and 2014. Of them, 140 individuals underwent surgery of CABG, 79 of TValvar (aortic, mitral or pulmonary). The sample showed a predominance of male, 150 (65.2%) with a mean age of  $60.0 \pm 10.1$  years old and 132 (60.2%) patients were elderly ( $\geq 60$  years old).

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They were from 64 municipalities of Rio Grande do Sul state, most of them from the municipalities of Ijuí, 37 (16%), Santa Rosa (6%), Santana do Livramento 14 (6%), São Borja 10 (4 3%), Uruguaiana (4.3%) and Santo Angelo 8 (3.5%). Among the occupation of individuals, most were farmers, 70 (30.4%), 41 retired (17.8%) and 13 drivers (5.7%).

Most patients were hypertensive, smokers in the past and had a history of CAD and AMI. By comparing these variables between the surgical procedures was statistically significant for patients undergoing CABG. Most patients also reported developing stress, physical inactivity, similar between groups of surgical patients. Anthropometric analysis observed that patients have fat accumulation in the abdominal region classified as preobesity by BMI and feature high coronary risk by conicity index, and there were no statistically significant differences except the abdominal circumference being higher in patients undergoing CABG (Table 1).

Table 1. Demographic and clinical characteristics of patients undergoing elective cardiac surgery. Jiuí (RS). Brazil

cardiac surgery. Ijuí (RS), Brazil							
Variables	Total	CABG	TValvar	_			
	n(%)	n(%)	n(%)	p≤0.05			
Demographic							
variables							
Age (M±SD)	60.0 ± 10.1	61.3 ± 8.1	57,2 ±12.8	0.01			
Male	150 (65.2)	102 (72.9)	43 (54.4)	0.04			
Risk factors							
HBP	170 (73.9)	115 (82.1)	49 (62.0)	0.02*			
Dyslipidemia	82 (35.7)	66 (47.1)	15 (19.0)	0.01*			
Diabetes Mellitus	65 (28.2)	51(36.4)	12 (15.2)	0.01*			
COPD	9 (3.9)	5 (3.6)	4 (5.1)	0.72			
Actual smoker	20 (8.7)	14 (10.0)	6 (7.6)	0.63			
Past smoker	118 (51.3)	86 (61.4)	29 (36.7)	0.01*			
Stress	135 (58.7)	89 (63.6)	40 (50.6)	0.06			
Sedentary	155 (67.4)	95 (67.9)	54 (68.4)	0.75			
AMI	78 (33.9)	64 (45.7)	9 (11.4)	0.01*			
CAD in the family	165 (71.7)	109 (77.9)	47 (59.5)	0.04*			
Anthropometric variables							
Weight (Kg)	77.0 ± 13.8	79.5 ±13.1	72,3±13,5	0.01*			
Height (cm)	165.2 ± 9.1	165.8±9.3	164,0±9,1	0.17			
WC (cm)	100.8 ± 11.4	103.2 ±9.5	96,4±12,9	0.01*			
IMC ( $Kg/m^2$ )	28.2 ± 4.5	$28.8 \pm 4.2$	$27,0 \pm 4,9$	0.24			
CI in Men	$1.34 \pm 0.3$	1.35 ± 0.2	$1,32 \pm 0,4$	0.50			
CI in Women	$1.37 \pm 0.3$	1.31 ± 0.2	$1,42 \pm 0,4$	0.60			

CABG: coronary artery bypass graft, TValvar: valve replacement surgery, HBP: high blood pressure, COPD: chronic obstructive pulmonary disease, AMI: acute myocardial infarction, CAD: coronary artery disease, WC: waist circumference, CI: conicity index, M $\pm$ SD: mean and standard deviation, N (%): number and percentage,\*: when p $\leq$  0,05.

Table 2 shows the results of Intra and postoperative characteristics of patients undergoing cardiac surgery in the Interior of Rio Grande do Sul, Brazil. The duration of cardiac surgery is about 3½ hours, no differences between the procedures. The clamping of the aorta is performed in both

procedures, and in surgical valve replacement was performed in a longer time, and the time of CPB. It was observed that 100% of patients used mediastinal drain. On average, the independent unit of hospital stay is similar in both groups of cardiac surgery, and the average hospital stay is six days.

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Table 2. Intra and postoperative characteristics of patients undergoing elective cardiac surgery. Ijuí (RS), Brazil

intra- and postoperative characteristics	Total	CABG	TValvar	p≤0,05
Surgery duration (min)	202.5±77.8	200.4±81.1	204.8±74.2	0.07
Aortic Clamping (min)	66.4 ± 25.4	56.8 ± 19.2	$78.8 \pm 26.7$	0.01*
ECC time (min)	89.9 ± 83.5	75.1 ± 25.7	111.0±130.0	0.02*
MV time (min)	608.4±253.9	633.9±304.8	570.0±143.7	0.06
Drain of mediastinum, n (%)	219 (100)	140 (100)	79 (100)	
Recovery rate:				
spontaneous n(%)	118 (51.3)	82 (58.6)	36(45.6)	0.05*
Shock n(%)	62 (27.0)	30 (21.4)	29(36.7)	0.08
ICCU duration (days)	2.5 ± 1.5	2.6 ± 1.9	2.5±0.9	0.62
Bed duration (days)	3.4 ± 1.6	3.3 ± 1.6	3.7±1.7	0.12
Total hospitalization time (days)	6.1 ± 2.3	6.1 ± 2.5	6.2±1.9	0.79

CABG: coronary artery bypass graft, TValvar: valve replacement surgery, CPB: cardiopulmonary bypass, VM: Mechanical Ventilation, ICCU: Intensive Cardiac Care Unit, M  $\pm$  SD: media and standard deviation, N (%): number and percentage. \*: when p  $\leq$  0,05.

Table 3 shows the complications that occurred in each postoperative between the total sample, surgical procedures OF CABG and TValvar. Respiratory and hemodynamic complications are more prevalent in post cardiac surgery, but with the evolution of hospital stay they decrease. In the first and second postoperative, CABG possessed a higher incidence of respiratory infections compared to the TValvar procedure. The same is observed in hemodynamic complications in the immediate postoperative period and the first postoperative day.

The dehiscence of the surgical wound was observed only in one (0.6%) patient in the fifth CABG PO, and only one patient showed

wound complication of lower limb on the fifth postoperative day. It is important to highlight in this study that most of the patients undergoing cardiac surgery had complications after surgery, and there was no difference in the percentage of complications from surgical procedures. Comparing CABG with TValvar and postoperative complications for each day of postoperative in-hospital, it was not observe a statistically significant difference (POI p=0,82; 1°PO p=0,08; 2°PO p=0,57; 3°PO p=0,31; 4°PO p=0,35; 5°PO p= 0,23; 6°PO p=0,08). The hospital discharge started from the fifth postoperative day, stressing again that the average hospital stay is 6 days in both surgeries.

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Table 3. Characterization of postoperative complications in CABG and TValvar according to the days of hospital patients undergoing elective cardiac surgery. Julí (RS), Brazil

POstoperative	PO I n(%)	elective cardiac 1° PO n(%)	2° PO n(%)	3° PO n(%)	4° PO n(%)	5° PO n(%)	6° PO n(%)
complications	T/CABGI/TVal	T/CABGI/TVal	T/CABGI/T	T/CABGI/TVal	T/CABGI/T	T/CABGI/T	T/CABGI/T
·	var	var	Valvar	var	Valvar	Valvar	Valvar
Neurologic	4(2)/3(3)/1(2)	3(2)/1(1)/2(3)	3(1,8)/1(0, 9)/ 2(3,1)	2(1)/1(1)/1(2)	2(1)/1(1)/ 1(2)	1(0,6) / 1(0,9) / -	- / - / -
Cardiac	2(1) / 2(1) / -	4(2)/2(2)/2(3)	2(1,2)/1(0, 9)/ 1(1,6)	2(1) / - / 2(3)	1(0,6)/ - /1(2)	1(0,6) / - / 1(2)	2(1)/ - /2(3)
Respiratory	22(13) / 14(14) / 8(12)	24(14)/20(19) / 4(6)	15(8,8)/12( 11,2)/ 3(4,7)	8(5)/4(4)/2(3)	3(2)/2(2)/1 (2)	3(2)/- / 3(5)	3(2)/1(1)/ 2(3)
Vascular	3(2) / 1(1) / 2(3)	2(1)/1(1)/1(2)	5(2,9)/2(1, 9)/ 3(4,7)	8(5) / - / -	2(1) / - / -	2(1)/1(1)/1 ,(2)	- / - / -
Digestive	1(0) / 1(1) / -	2(1)/2(2)/-	2(1,2)/2(1, 9)/ 9(0)	- / - / -	4(2)/ - /2(3)	3(1,8)	- / - / -
Renal	- / - / -	- / - / -	- / - / -	- / - / -	- / - / -	- / - / -	1(0,6)/ - / 1(2)
Hemodynamic	20(12)/14(14) /6(9)	21(12)/17(16) /4(6)	31(18)/20( 19)/ 11(17)	8(4,8)/3(2,9)/ 5(7,9)	4(2)/3(3)/1 (2)	3(2)/1(0,9) /2(3)	- / - / -
Vasc + Hemod	2(1) /1(1) /1(2)	- / - / -	- / - / -	- / - / -	- / - / -	- / - / -	- / - / -
Resp. + Hemod.	2(1) /1(1) /1(2)	5(3)/3(3)/2(3)	4(2,3)/3(2, 8)/ 1(1,6)	1(0,6)/- /1(1,6)	1(0,6)/- /1(2)	1(0,6)/- /1(2)	1(0,6 )/- /1(2)
Neuro + Hemod.	2(1) /1(1)/1(2)	1(0,6) / - /1(2)	- / - / -	- / - / -	- / - / -	- / - / -	- / - / -
Neuro.+ Resp.	1(0) / - / 1(2)	- / - / -	- / - / -	1(0,6)/- /-	- / - / -	- / - / -	- / - / -
Cardio + Hemod.	- / -	1(0,6) / - /1(2)	1(0,6) / 1(0,9) / -	- / - / -	- / - / -	- / - / -	- / - / -
Digestive + Resp	- / - / -	1(0,6) / - /1(2)	- / - / -	- / - / -	- / - / -	- / - / -	- / - / -
Digetive + Hemod	- / - / -	- / - / -	1(0,6) / - / 1(2)	- / - / -	- / - / -	- / - / -	- / - / -
Hemo+Neuro+ Resp	- / - / -	- / - / -	1(0,6) / 1(0,9) / -	1(0,6)/1(1,0)/ 0(0)	- / - / -	- / - / -	- / - / -
Hemo+Cardio+ Resp+Ren	- / - / -	- / - / -	- / - / -	1(0,6)/1(1,0)/ 0(0)	- / - / -	- / - / -	- / - / -
Resp + Cardio	- / - / -	- / - / -	- / - / -	1(0,6)/1(1,0)/ 0(0)	1(0,6)/1(1, 1)/0 (0,0)	- / - / -	- / - / -
Without complications	110(65)/66(64 )/ 44(68)	109(63)/62(57 )/ 47(72)	106(62)/64 (60)/ 42(66)	142(85)/92(89 )/ 50(79)	153(92)/97 (93)/ 56(89)	110(65)/74( 70)/ 36(57)	91(56)/63( 62)/ 28(47)
Hospital discharge	- / - / -	- / - / -	- / - / -	- / - / -	- / - / -	46(27)/27(2 4)/ 19(30)	64(40)/38( 37)/ 26(43)
Total evaluated	169(100)/114( 100)/ 65(100)	173(100)/108( 100)/ 65(100)	171(100)/1 07(100)/ 64(100)	167(100)/104( 100)/ 63(100)	167(100)/1 04(100)/ 63(100)	169(100)/1 06(100)/ 63(100)	162(100)/1 02(100)/ 60(100)
Not evaluated	50(23)/36(26) / 14(18)	46(21)/32(23) / 14(18)	48(21,9)/3 3(23,6)/ 15(19)	52(24)/36(26) / 16(20)	52(24)/36( 26)/ 16(20)	50(23)/34(2 4)/ 16(20)	57(26)/38( 27)/ 19(24)

Data presented in absolute and relative frequencies. Answers: respiratory, Hemod: hemodynamic, digest: digestive, Card: cardiac. Ren: renal, number of patients with postoperative complications. FO MI: Wound lower limb surgery. / - /: Zero values.

# DISCUSSION

From the results of this study, it was found that most of the sample are male, with the presence of several associated cardiovascular risk factors, including hypertension, smoking in the past and family history of CAD, being more significant in the procedure of CABG. The stress and sedentary lifestyle factors were also observed in most patients in both groups.

Similar results were found in other studies that showed the predominance of male patients underwent surgical treatment, with a mean age of 61.2 years old, cardiovascular risk factor more prevalent of hypertension, followed by dyslipidemia, family history of CAD, prior smoking and diabetes mellitus, and

in more than half of the study population had a history of previous AMI.<sup>12</sup>

As similar results of studies carried out in different regions of the country, as in Goiânia/GO,<sup>17</sup> Ribeira Preto/SP<sup>18</sup> and Joinville/Santa Catarina,<sup>19</sup> it was shown that even being in different regions, Brazil has the same characteristics as the presence risk factors.

Among the occupation, most of the population is retired or farmers, explaining to the population is older, and the region present a strong predominance in agricultural activities, and the European migratory currents that have taken up residence in the state of Rio Grande do Sul.<sup>20</sup>

In the anthropometric analysis, it was showed that the patients had fat

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accumulation in the abdominal region classified as pre-obesity by BMI and showed high coronary risk by conicity index, there were no statistically significant differences, except for the waist circumference in which was higher in patients undergoing CABG.

Studies say that the BMI of most patients participating in a cardiac rehabilitation program were overweight and (77.5%),<sup>21</sup> similar to this study, found in analysis of the nutritional profile of 59 adults with CVD in both genders the high prevalence overweight (78.54% VS. respectively); 22 as well as another study found average values of WC (95.5 cm in men and 96 cm in women) when they studied 2179 individuals, which although high, they were lower than this study.<sup>23</sup>

Regarding the surgical and postoperative variables, the mean duration of surgery time was 3 hours and a half, time on mechanical ventilation for 10 hours and the length of hospital stay of 6 days. In the analysis of mechanical ventilation time, it was around 10 hours; mean time also observed in other studies the average duration of MV around 12 hours and 17 hours. <sup>24-5</sup>

Hospitalization in ICCU had an average of two days. This finding may be explained by high ICCU routines, and patients undergoing surgery, who do not have any complications and are in stable condition, are high on the 2<sup>nd</sup> day after surgery; also, the time spent in bed was on average of three days and total hospital stay was six days, patients emphasizing that physiotherapy team of care during the hospital stay both ICCU as the beds daily, three times a day during hospitalization in ICCU and twice a day in the hospital in beds, which is a contributing factor to reducing hospital stay, and have received preoperative physiotherapy guidelines.

In the literature, most studies showed a greater number of days of hospitalization compared to this study. The total length of hospital was at least ten days  $(73.1\%)^8$  and the Physiotherapy has proved relevant in the post-operative recovery, especially in the mobility category, resulting in an average hospital stay of  $8.9 \pm 2.4$  days, showing that the majority (35.8%) were discharged on the  $7^{th}$  postoperative day.<sup>26</sup>

Complications from heart surgery can relate to pre-existing diseases such as previous pulmonary disease, chronic pulmonary obstructive disease (COPD), smoking, advanced age, nutritional status, obesity, diabetes.<sup>27</sup> In this study the most frequent postoperative complications were respiratory and hemodynamic, focusing on CABG among the first few days after surgery. The rate of respiratory complications after heart surgery is between 7 and 49%. According to some authors, 60% of patients were revascularized, and of these, 32% had respiratory complications, as well as another study reported a rate of 30% of postoperative complications.

The main limitation of the study was the fact that the database used was a single center. Despite the vast experience, it cannot be said that the results are representative of the national scene. However, the study was retrospective, with a four-year period of data collection for a significant sample may lead to accumulation of bias arising from changes in the profile of patients.

### CONCLUSION

The results help to establish the clinical and demographic characteristics of the patients currently undergoing elective surgery for CABG and valve replacement in the Northwest RS, Brazil, little-known data in the literature. Patients undergoing cardiac surgery have some associated cardiovascular risk factors, including hypertension, smoking in the past and family history of CAD, being more significant in CABG procedure. The stress and sedentary lifestyle factors were also observed in most patients in both groups, as well as coronary high risk.

The results of the variables of Intra and postoperative surgical procedures showed no differences between the types of surgery, and the average duration of the procedure was 3 and a half hours and the hospital stay was 6 days. The most frequent postoperative complications were respiratory and hemodynamic, focusing on CABG among the first few days after surgery.

From this study, it is seen that the attention should be given to preventive health activities since the high cardiac risk population. Intra and postoperative clinical characteristics are similar to other studies.

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Eliane Roseli Winkelmann Rua do Comércio 3000 Bairro Universitário DCVida/UNIJUÍ Cx. Postal 383

CEP 98700-000 — Ijuí (RS), Brazil