



## Original Article

# Total hip arthroplasty complications in patients with or without controlled diabetes mellitus during hospitalization<sup>☆</sup>



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## ABSTRACT

**Introduction:** Total hip arthroplasty (THA) is a procedure that aims to restore the function of the hip joint. Diabetes mellitus (DM) is one of the most prevalent comorbidities among patients undergoing THA. DM involves various immunological and metabolic aspects, which lead to limitations and surgical complications.

**Objective:** To evaluate the association between THA complications and controlled DM during hospitalization period.

**Methods:** Cross-sectional research through the analysis of retrospective records of a private hospital in Salvador, Bahia. The chi-squared and Fisher's exact tests were used in SAS statistical program.

**Results:** Most patients were elderly females. The most prevalent comorbidities in the sample were hypertension and diabetes. The most frequent underlying pathology in the sample was coxarthrosis; among patients with DM, it was femoral neck fracture. The most common complications were changes in the hemolymphopoietic system, among which anemia was the most frequent complication. Cardiovascular, nervous, and blood glucose complications were positively associated with controlled DM. In turn, hemolymphopoietic, genitourinary, digestive, electrolyte, and infectious complications were not associated with DM. Having DM was a protective factor for thermal complications. There was no statistically significant difference between patients that had or did not have DM in each complication group studied.

**Conclusion:** Patients with controlled DM did not present more complications than those without DM during hospitalization in the post THA.

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## Complicações pós-artroplastia total de quadril em portadores e não portadores de diabetes mellitus controlado durante a internação

### R E S U M O

#### Palavras-chave:

Artroplastia total de quadril  
Complicações pós-operatórias  
Diabetes mellitus

**Objetivo:** Avaliar a associação entre as complicações pós-ATQ e DM controlado no período da internação.

**Métodos:** Pesquisa de corte transversal por meio da análise de prontuários retrospectivos de um hospital particular em Salvador (BA). Usaram-se os testes qui-quadrado e exato de Fisher no programa estatístico SAS.

**Resultados:** A maioria dos pacientes era do sexo feminino e idosa. As comorbidades mais prevalentes da amostra foram hipertensão arterial sistêmica e DM. A patologia de base mais frequente na amostra foi coxartrose; já entre os pacientes com DM, foi fratura do colo do fêmur. As complicações mais comuns foram alterações do sistema hemolinfopoiético. Dentre essas anemia foi a complicação mais frequente. As complicações do aparelho cardiovascular, do sistema nervoso e as glicêmicas tiveram associação positiva com o DM controlado. Já as complicações hemolinfopoiéticas, geniturinárias, digestórias, eletrolíticas e infecciosas não apresentaram associação com DM. Ser portador de DM foi um fator protetor de complicações térmicas. Não houve diferença estatisticamente significativa entre os pacientes portadores e não portadores de DM em nenhum dos grupos de complicações estudados.

**Conclusão:** Os pacientes portadores de DM controlado não apresentaram mais complicações dos que os pacientes não portadores de DM durante a internação no pós-operatório da ATQ.

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## Introduction

Total hip arthroplasty (THA), a procedure of replacement of the hip joint with a prosthesis, is a relatively safe intervention. The increased life expectancy has elevated the number of procedures.<sup>1-3</sup> In the United States, more than 168,000 THAs and 30,000 implant substitutions are performed per year. In Brazil, there are few epidemiological data.<sup>4,5</sup>

Coxarthrosis is the most common indication for THA. Other common indications are rheumatoid arthritis, fractures, and necrosis of the femoral head.<sup>6-8</sup> THA aims to relieve pain and improve functional capacity.<sup>1,9</sup> Complications involve surgery infections, thromboembolism, and anemia, among others. Infections are the most feared, prevalent, and studied complications.<sup>9</sup> Diabetes mellitus (DM), hypertension (SAH), and heart diseases are the most prevalent comorbidities among THA patients.<sup>10,11</sup>

DM prevalence in Brazil is 7.6%,<sup>12</sup> and is initially characterized by hyperglycemia. It is the result of anomalies in the insulin secretion and/or action. It involves immune and metabolic aspects, which facilitate infections and reduce the repair and healing ability. Chronic complications confer a high degree of morbidity and mortality. Naturally, alterations vary with the intensity and level of control of the disease. Therefore, it is important to assess the health condition of these patients and the need for surgical intervention, and to analyze the cost-benefit of surgeries such as THA.<sup>13,14</sup>

There is a considerable lack of information about THA complications in patients with DM.<sup>13</sup> Thus, the analysis of

the profile of patients and their post-THA complications can contribute to the development of protocols, point to associations, and assist the orthopedist in the indication of THA for diabetic patients. Therefore, this study aimed to evaluate the association between post-THA complications with and without controlled DM during the period of hospitalization.

## Materials and methods

This was a cross-sectional study through retrospective analysis of medical records of a private hospital that specializes in the treatment of orthopedic patients, primarily from middle- and upper-class, which belongs to the private health-care network. In this hospital, two surgical teams perform THA.

The study population comprised hospital patients undergoing THA. The calculated sample size, with a confidence interval of 95% and a sample error of 5%, was 84 patients. Permuted randomization was done in blocks of patients, so that sample was composed of the same number of patients operated by each surgical team, 42 each. The study included patients who underwent THA from January 2013 to December 2014 and were drawn. Patients with incomplete or lost records in the hospital database were excluded.

The criteria for THA indication was degenerative, inflammatory, and/or traumatic hip pathologies. Diagnosis was always made by an orthopedic physician through radiographic examination (significantly reduced joint space associated with

areas of sclerosis and osteophyte formation and/or proximal femur fracture), and clinical examination (intense pain that impairs function and gait).

Collected variables were: gender, age, smoking, alcohol use, illicit drug use, pre-existing chronic diseases (DM, SAH, dyslipidemia, and obesity), criteria for THA indication, type of surgery (primary THA or revision THA), operated side, use of cement, death during hospitalization, and clinical postoperative complications during hospitalization.

Complications were classified into groups: cardiovascular system, respiratory system, digestive system, genitourinary tract, nervous system, of the extremities, hemolymphopoietic system, electrolyte, infectious, thermal, glucose, sleep disorders, skin disorders, and pain. The most prevalent groups were used for statistical analysis.

A member of the Information Technology (IT) department of the hospital conducted an active search for patients in the medical records system who had undergone THA surgery between 2013 and 2014. This search led to the record numbers of patients who underwent this surgery within this period.

Later, three medical students researchers involved in this project were trained by a member of the IT department's medical records system. These researchers took turns to collect data. Patient records and variables were inserted into Microsoft® Excel® 2011 for Mac, version 14.5.7, therefore creating the database for this research.

In the descriptive statistics, absolute and relative frequencies were used for nominal variables. Numerical variables, whether discrete or continuous, were analyzed according to measures of central tendency (mean or median) and dispersion (standard deviation and quartiles), considering the dependence of the sample distribution.

In the analytical statistics, the prevalence ratio was calculated with a 95% confidence interval (CI). An error of 5%  $\alpha$  was adopted (statistical significance:  $p < 0.05$ ). As the variables were nominal, the chi-squared and Fisher's exact tests were used. The latter was used when 50% of the  $2 \times 2$  table cells had counts lower than five, as in that case the chi-squared test is not valid.

The program used for this analysis was the Statistical Analysis System® (SAS) version 9.4, a software developed by the SAS Institute for advanced analysis, multivariate analysis, business intelligence, data management, and predictive analytics.

This study was approved by the Research Ethics Committee of the Instituto Mantenedor de Ensino Superior da Bahia (IMES), CAAE No. 49260815.0.0000.5032, in order to comply with Resolution No. 466/2012 of the Brazilian National Health Council. It was not necessary to elaborate and sign an informed consent form, as this was a study of secondary data (medical charts).

## Results

Out of the 84 patients, one was excluded due to incomplete medical chart. Thus, the final sample had 83 patients. Of these, 24 (28.9%) had DM; 66.3% of the total sample and 75% of the DM patients were female. SAH was present in

**Table 1 – Categorical epidemiological variables of patients undergoing THA, with and without DM during hospitalization in a hospital in Salvador, BA, Brazil, from January 2013 to December 2014.**

Characteristics	DM		Total	p-Value
	Yes	No		
Sex	24 (28.9%)	59 (71.1%)		0.28 <sup>a</sup>
Female	18 (75%)	37 (62.7%)	55 (66.3%)	
Male	6 (25%)	22 (37.3%)	28 (33.7)	
Smoking	3 (12.5%)	3 (5.1%)	6 (7.2%)	0.35 <sup>b</sup>
Alcohol consumption	3 (12.5%)	6 (10.3%)	9 (10.8%)	0.72 <sup>b</sup>
Use of illicit drugs	0	1 (1.7%)	1 (1.2%)	>0.9 <sup>b</sup>
Obesity	4 (16.7%)	2 (3.4%)	6 (7.2%)	0.055 <sup>b</sup>
Dyslipidemia	9 (37.5%)	8 (13.6%)	17 (20.5%)	0.032 <sup>b</sup>
SAH	21 (87.5%)	32 (54.2%)	53 (63.9%)	0.004 <sup>a</sup>
THA indication				0.019 <sup>b</sup>
Coxarthrosis	8 (34.8%)	38 (64.4%)	46 (55.4%)	
Femur fracture	14 (60.9%)	18 (30.5%)	32 (38.6%)	
Other arthrosis	0	2 (3.4%)	2 (2.4%)	
Osteonecrosis	0	1 (1.7%)	1 (1.2%)	
Osteomyelitis	1 (4.4%)	0		
Surgery				0.35 <sup>b</sup>
Primary	23 (27.7%)	50 (60.2%)	73 (88%)	
Secondary	1 (4.2%)	9 (15.3%)	10 (12%)	
Side				0.82 <sup>a</sup>
Right	14 (58.3%)	36 (61%)	50 (60.2%)	
Left	10 (41.7%)	23 (39%)	33 (39.8%)	
Use of cement	8 (33.3%)	23 (39%)	31 (37.4%)	0.63 <sup>a</sup>
Death	1 (1.2%)	2 (2.4%)	3 (3.6%)	1 <sup>b</sup>

<sup>a</sup> Pearson's chi-squared test.

<sup>b</sup> Fisher's exact test.

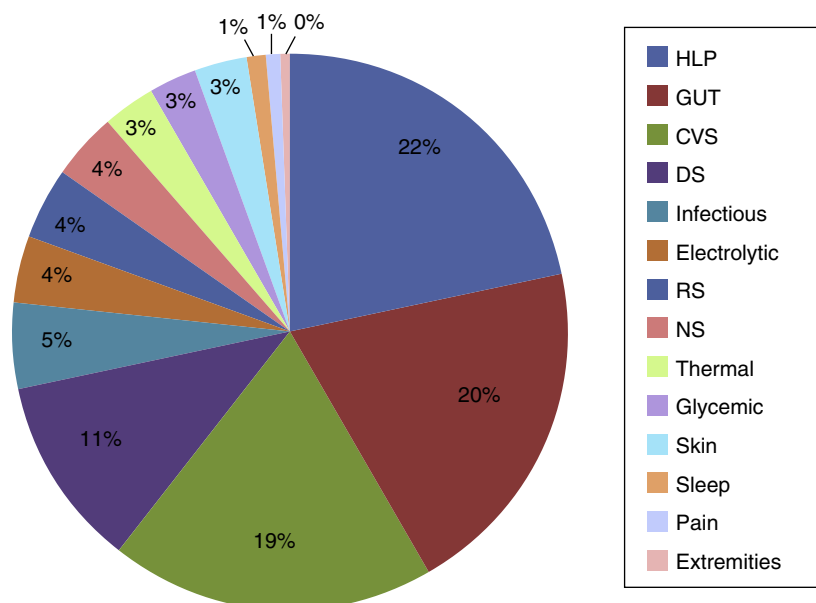
63.9% of the sample and in 87.5% of patients with DM. The preoperative diagnosis of coxarthrosis was made in 55.4% of the sample; among diabetics, femoral neck fracture was the indication of the THA in 60.9% of patients ( $p=0.019$ ; Table 1).

Mean age was 66.8 years ( $\pm 15.73$ , range: 33–95); the mean age of DM patients was 72.8 ( $\pm 1.85$ , range: 41–89) and that of non-DM patients was 64.3 ( $\pm 16.32$ , range: 33–95).

All patients received prophylaxis for deep venous thrombosis and antibiotic prophylaxis in accordance with the current literature.<sup>14,15</sup>

In the sample, 79.5% of patients had at least one clinical complication during the hospitalization period, whether or not related to the surgical procedure, for a total of 229 complications. Fig. 1 shows the frequencies of complications, which were grouped and are described below. Some patients had more than one complication from the same group.

The hemolymphopoietic system showed 21.5% of complications (48). Among these were observed anemia secondary to severe bleeding (92%), thrombocytopenia (6%), and leukocytosis (2%). In the genitourinary tract, 45 complications (19.7%) were observed: urinary retention (67%), urinary tract infection (UTI; 20%), anuria (4%), acute renal failure (4%), polyuria (2%),



**Fig. 1 – Frequencies of hemolymphopoietic (HLP), genitourinary (GUT), cardiovascular (CVS), digestive (DS), electrolytic, respiratory (RS), nervous system (NS), infectious, thermal, glycemic, skin, sleep, pain, and extremities complications in patients undergoing THA (229 complications) during in a hospital in Salvador, BA, Brazil from January 2013 to December 2014.**

and retrovesical fistula (2%). The cardiovascular system had 18.3% of complications (42): hypotension (43%), hypertensive peak (17%), hypovolemic shock (14%), tachycardia (7%), cardiac arrest (5%), septic shock (2%), acute myocardial infarction (2%), atrial fibrillation (2%), tachyarrhythmia (2%), bradycardia (2%), and hemodynamic instability (2%).

The digestive tract presented 10.9% of the complications (25): constipation (84%), epigastric pain (4%), dysphagia (4%), vomiting (4%), and diarrhea (4%). Infections happened ten times (4.5%); among these, the following were observed: postoperative wound infection (40%), catheter infection (20%), osteomyelitis (20%), oropharyngeal infections (10%), and sepsis (10%). Electrolyte changes occurred nine times (3.9%), as hyponatremia (78%) and hypomagnesemia (22%). In the respiratory system, nine complications (3.9%) were observed: desaturation (11%), dyspnea (11%), acute respiratory failure (11%), bronchial aspiration (11%), pneumonia (11%), pleural thickening (11%), atelectasis (11%), apical nodules (11%), and bilateral pleural effusion (11%). In the nervous system, eight complications (3.5%) were observed: decreased level of consciousness (38%), ischemic encephalovascular disease (12.5%), delirium (12.5%), encephalopathy (12.5%), hypothyria (12.5%), and hypoactivity (12.5%). Thermal complications were observed seven times (3.1%): fever (86%) and hypothermia (14%). Glucose complications were observed six times: hyperglycemia (83%) and hypoglycemia (17%).

Skin disorders were observed six times (2.6%): eschar (17%), ecchymoses (17%), fistula (17%), hematic collection (17%), bleeding from the surgical wound (17%), and lesion in the scrotum (17%). Insomnia was the only sleep disturbance reported,

having occurred in two cases (0.9%). Pain was also only described in the medical records twice (0.9%), both in the operated limb. Among the complications of the extremities, there was a single case of lower limb edema (0.4%).

Table 2 presents analytical statistics. For this, the nine most prevalent groups of complications in the patients of the sample (83) were used. A positive association was observed between the groups of cardiovascular system, nervous system, and glycemic complications. There was no association between groups of hemolymphopoietic, genitourinary, digestive, electrolytic, and infectious complications. There was an inverse association in thermal complications. There was no statistically significant difference between patients with and without DM in any of the groups of complications studied.

## Discussion

Patients undergoing THR in the study sample were mostly elderly women. SAH was the most frequent comorbidity. The most frequent underlying pathology was coxarthrosis; in patients with DM, femoral neck fracture. The vast majority of patients underwent primary THA on the right side. The most common complications were alterations in the hemolymphopoietic system; among these, anemia was the most common complication. The cardiovascular system, nervous system, and glycemic complications had a positive association with controlled DM. There was no statistically significant difference between patients with and without DM in any of the groups of complications studied.

**Table 2 – Hemolymphopoietic, genitourinary, cardiovascular, digestive, electrolytic, nervous system, infectious, thermal, and glucose complications in patients undergoing THA in patients with and without DM (83 patients) during hospitalization in a hospital in Salvador, BA, Brazil, from January 2013 to December 2014.**

Complications	DM				Total		p-Value	PR	CI (95%)
	Yes		No		n	%			
	n	%	n	%					
Hemolymphopoietic							0.89 <sup>a</sup>		
Yes	13	15.7	31	37.4	44	53		1	0.7–1.6
No	11	13.3	28	33.7	39	47			
Genitourinary							0.37 <sup>a</sup>		
Yes	10	12.1	31	37.4	41	49.4		0.8	0.5–1.3
No	14	16.9	28	33.7	42	50.6			
Cardiovascular							0.18 <sup>a</sup>		
Yes	11	13.3	18	21.7	29	34.9		1.5	0.8–2.7
No	13	15.7	41	49.4	54	65.1			
Digestive							0.85 <sup>a</sup>		
Yes	7	8.4	16	19.3	23	27.7		1.1	0.5–2.3
No	17	20.5	43	51.8	60	72.3			
Electrolytic							0.71 <sup>b</sup>		
Yes	3	3.6	6	7.2	9	10.8		1.2	0.3–4.5
No	21	25.3	53	63.9	74	89.2			
Nervous system							0.41 <sup>b</sup>		
Yes	3	3.6	4	4.8	7	8.4		1.8	0.4–7.6
No	21	25.3	55	66.3	76	91.6			
Infectious							1.00 <sup>b</sup>		
Yes	2	2.4	5	6.0	7	8.4		1	0.2–4.7
No	22	26.5	54	65.1	76	91.6			
Thermal							0.67 <sup>b</sup>		
Yes	1	1.2	6	7.2	7	8.4		0.4	0.1–3.2
No	23	27.7	53	63.9	76	91.6			
Glucose							0.35 <sup>b</sup>		
Yes	3	3.6	3	3.6	6	6.2		2.5	0.5–11.3
No	21	25.3	56	67.5	77	92.8			
Total	24	28.9	59	71.1	83	100			

PR, prevalence ratio.

<sup>a</sup> Pearson's chi-squared test.<sup>b</sup> Fisher's exact test.

The results show similar epidemiological characteristics to those of previously published studies; that is, most patients were aged over 65 years, the prevalence of female osteoarthritis was the most common indication for surgery, and SAH was most frequent clinical comorbidity.<sup>1,10,16–18</sup>

Of the patients, 28.9% had a diagnosis of DM. The literature varies regarding the prevalence of DM: from 34.2% to 9.2%.<sup>10,11</sup> The highest mean age of patients with DM (six years older) is justified by the fact that the incidence of this pathology intensifies with increasing age.<sup>19</sup> A literature review showed reduction in the surgical site infection rate, mortality, and length of hospitalization in patients with controlled blood glucose.<sup>14</sup>

In the present study, the prevalence of SAH was 64%; similar studies reported 50.4%<sup>10</sup> and 45.9%.<sup>11</sup> There was no statistically significant difference between DM and comorbidities: SAH ( $p = 0.004$ ) and dyslipidemia ( $p = 0.03$ ). In turn, obesity had a  $p$ -value that was very close to statistical significance ( $p = 0.06$ ). Therefore, an association of DM with SAH and dyslipidemia was observed in this population; probably many of

the patients had a diagnosis of metabolic syndrome, but this diagnosis was not documented in the medical records of any patient.

The ICD-10 that was most declared as the main diagnosis was M16.9 (unspecified coxarthrosis), in 55.42% of the sample. Other studies also observed the diagnosis of coxarthrosis as the primary indication of THA, one with 49.1% and the other with 92.4%, respectively, of patients who underwent THA.<sup>10,11</sup> In the present study, among patients with DM, the ICD-10 most commonly cited was the S72.0 (fracture of neck of femur) in 60.87% of patients, a statistically significant difference ( $p = 0.02$ ). No data on the baseline diagnosis for THA indication in patients with DM were retrieved in the literature. However, it is known that diabetic patients have low bone metabolism, decreased bone formation and, to a lesser extent, decreased reabsorption. These factors lead to an increased risk of fractures in DM patients. The mechanism is unknown and likely to be multifactorial.<sup>20,21</sup>

The most performed surgery was primary THA, both in the overall sample (88%) and in patients with DM (96%). As in other



studies, secondary THA revision accounted for a minority of procedures. In other studies, the frequency of primary THA was 92.4% and 98%, respectively.<sup>10,11</sup>

Right side was the most operated within total sample (60.24%) and in DM patients (58.33%). The literature is divergent as to the most operated side in THA; in some studies, the involvement of the left or right side was similar.<sup>22,23</sup> In turn, in some studies the most operated side was the right, 69.2% and 55.6% respectively.<sup>24,25</sup> Another survey found a slight predominance of the left side, with 53.5%.<sup>26</sup> Bone cement was used in 37.35% of the sample. Piano et al.<sup>11</sup> used cement in 48% of their THA patients.

In the present sample, the mortality rate was 3.6%, with three deaths. One patient developed osteomyelitis, later progressing with sepsis and then cardiac arrest, having died on the 115th day of hospitalization. One patient had a hypovolemic shock and died in the first postoperative day. The third had a septic shock, followed by ventricular tachycardia and cardiac arrest, having died on the 15th postoperative day. Another study found a mortality rate of 0.1% in a sample of 344 patients undergoing THA.<sup>10</sup> There was no statistically significant difference between the deaths of patients with and without DM ( $p=1$ ) in the present study. A hip fracture post-correction mortality survey showed a correlation between higher number of clinical comorbidities, longer hospital stays, and use of general anesthesia in surgery with higher mortality.<sup>22</sup> However, there were no data about the mortality of diabetic patients undergoing THA.

Although THA is reported in the literature as a relatively safe intervention, 79.5% of patients had some complication, in a total of 229 clinical complications during hospital stay of patients (related or unrelated to surgery). This demonstrates that surgeons should be cautious. A study with a sample of 334 patients who underwent THA found 76 clinical complications.<sup>10</sup>

The most prevalent infections were UTI in nine patients (10.8%), followed by wound infection in four (4.8%). A review that addressed the causes and control of infections in surgical patients also found UTI as the most common infection in surgical patients.<sup>14</sup> A study of nosocomial infections in patients undergoing THA presented incidence of 15.1%; wound infection was the most common (13%), followed by UTI (2.1%).<sup>27</sup> Authors stated that UTI has lower mortality; that surgical wound infection is the second in frequency, but the third in costs; and that hematologic infection and pneumonia are less common, but with high mortality and high costs.<sup>14</sup> Although the literature describes DM as a risk factor for infections,<sup>28</sup> no statistically significant difference was observed in the present study for patients with and without DM. A possible explanation is because preoperative glycemic control is associated with a decrease in infectious complications in different types of surgery.<sup>14</sup>

After UTI, which was the most prevalent, Lenza et al.<sup>10</sup> found the following as complications: surgical site infection (1.5%), respiratory failure (1.5%), and anemia (1.5%). In the present study, respiratory failure occurred in one patient (1.2%) and anemia was the most common complication, in 44 (53%). This indicates that patients lose a significant amount of blood during surgery. Finding the risk factors for this complication

is important for effective prevention. The reduction in cases of anemia due to bleeding also prevents other conditions, e.g., hypovolemic shock, which was observed in five patients (6%) in the present study.

One study found deep vein thrombosis as a complication in THA in 1.2% of patients.<sup>10</sup> In the present study, there were no cases of deep vein thrombosis, which probably indicates that the protocol followed by the institution for this pathology is efficient.

An observational study of 202 elderly patients who underwent THA and total knee arthroplasty observed that the higher the age, the higher the incidence of complications.<sup>29</sup> This confirms the high rate of complications in the present study, since the mean age was high, 66.8 years ( $\pm 15.73$ , range: 33-95) in the total sample and 72.8 years ( $\pm 11.85$ , range: 41-89) in patients with DM.

The hemolymphopoietic, genitourinary, digestive, electrolytic, and infectious complication groups had a prevalence ratio of approximately one. This indicates that the prevalence rate of complications in exposed and unexposed groups is identical, i.e., there is no association.

The complications of the cardiovascular system and nervous system showed a prevalence rate of approximately two, and glycemic complications, of approximately three. Thus, there is a positive association or increased risk among those exposed to the factor studied when compared with those unexposed. Therefore, patients with DM had a two-fold increased risk for complications of the cardiovascular system and nervous system, and three times more glycemic complications when compared with patients without DM.

The prevalence ratio of thermal complications was approximately zero, i.e., there is an inverse association or a decreased risk among those exposed to the factor studied, which is the so-called protection factor. Thus, having DM was a protective factor for thermal complications.

There was no statistically significant difference between patients with and without DM in any of the groups of complications studied. This means that the chance of this difference between means be due to chance (and not a result of the DM) is above 5% (alpha error). Therefore, the null hypothesis could not be rejected, as there was not strong enough evidence to prove that the null hypothesis was false. The confidence interval also shows that the groups are similar, proving that there is no difference between the groups. Thus, it can be inferred that patients with controlled DM did not present more complications than those without DM in the post-operative period of THA, during hospitalization.

When describing characteristics of patients undergoing THA in a private hospital, it is essential to compare with other hospitals. This analysis is complex due to the diversity of the population, description of the methods, study design, study periods, and different healthcare systems. However, cross-sectional and qualitative analyses are essential to improve healthcare in each of the populations.<sup>10</sup> Data from this study may be useful in formulating strategies to reduce rates of complications in patients with DM undergoing THA, in addition to helping the hospital to reduce costs. The findings can be used for other populations with similar characteristics.

There are limitations to the present results. Firstly, data were analyzed retrospectively from the database, which leads to some questions about its collection. Secondly, a cross-sectional study is descriptive, hence causal inferences are impossible. Other factors may also have influenced the complications of THA. There is no presumption that the features of this sample will remain the same. Due to the design of this study and small sample size, the authors recommend that further studies involving larger sample sizes of patients from several centers should be conducted.

## Conclusion

The results of this study showed that there was no statistically significant difference between the post-THA complications in patients with and without controlled DM during the period of hospitalization. With these results, it can be inferred that the orthopedist may indicate THA for their controlled diabetic patients after taking standard care measures. As controlled diabetic patients do not present more complications, a different protocol or more cautious measures are not required. Patient can be warned that THA does not bring higher risk for individuals with controlled diabetes than for the non-diabetic.

## Conflicts of interest

The authors declare no conflicts of interest.

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