COMPLICATIONS OF INTRA-AORTIC BALLOON IN A COHORT OF HOSPITALIZED PATIENTS: IMPLICATIONS FOR NURSING CARE[1]

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Objectives: To describe complications associated to the use of intra-aortic balloon pumps (IABP), and their relationship with dwelling time, presence of risk factors/comorbidities, and nursing records. Methods: Retrospective cohort study, in which medical records were analyzed through the completion of specifically designed forms. Results: In total, 104 patients were included, with mean age 65±11 years, 52% men; 26 (25%) of them presented vascular complications, more frequently ischemia (25%); peripheral vascular disease was the risk factor/comorbidity more frequently related to complications (56.3%; p=0.003). Nursing records showed that the use of catheter was recorded in 30 cases (29%), and the patient's clinical situation after its removal in 28 cases (27%). Conclusion: This study showed that the frequency of complications related to IABP is high. Considering risk factor/comorbidity factors, peripheral vascular disease was significantly associated to complications. Nursing records were sub-optimal.

DESCRIPTORS: cohort studies; intra-aortic balloon pumping; nursing care

COMPLICACIONES DEL BALÓN INTRAAÓRTICO EN UNA COHORTE DE PACIENTES HOSPITALIZADOS: IMPLICACIONES PARA LA ASISTENCIA DE ENFERMERÍA

Este estudio tuvo como objetivos describir las complicaciones provenientes de la utilización del balón intraaórtico (BIA), relacionándolas con el tiempo de permanencia, con la presencia de factores de riesgo/enfermedades concomitantes y con los registros de enfermería. Se utilizó como método la cohorte histórica, con análisis de fichas por medio del llenado de un instrumento construido específicamente para el estudio. Después de la evaluación de 104 pacientes, edad promedio 65±11, 52% sexo masculino, los resultados mostraron que 26 (25%) presentaron complicaciones vasculares, siendo la isquemia (25%) la más incidente; entre los factores de riesgo/enfermedades concomitantes, el que más se relacionó con complicaciones fue la enfermedad vascular periférica (56,3%, p=0,003). En lo que se refiere a las evaluaciones de enfermería, 30 (29%) presentaban registro del uso del catéter, y 28 (27%) relataban el estado clínico del paciente después de su retirada. Se concluye que este estudio demostró que el índice de complicaciones es todavía alto cuando relacionado al BIA. Entre los factores de riesgo/enfermedades concomitantes, la enfermedad vascular periférica fue significativamente relacionada con complicaciones. Los registros de los enfermeros no fueron exhautivos.

DESCRIPTORES: estudios de cohortes; contrapulsador intraaortico; atención de enfermería

COMPLICAÇÕES DO BALÃO INTRA-AÓRTICO EM UMA COORTE DE PACIENTES HOSPITALIZADOS: IMPLICAÇÕES PARA A ASSISTÊNCIA DE ENFERMAGEM

Este estudo teve como objetivos descrever as complicações decorrentes da utilização do balão intra-aórtico (BIA), relacionando-as com o tempo de permanência, com a presença de fatores de risco/comorbidades e com os registros de enfermagem. Utilizou-se como método a coorte histórica, com análise de prontuários por meio de preenchimento de instrumento específico para o estudo. Após avaliação de 104 pacientes, idade média 65±11, 52% sexo masculino, os resultados mostraram que 26 (25%) apresentaram complicações vasculares, sendo a isquemia (25%) a mais incidente; entre os fatores de risco/comorbidades, o que mais se relacionou com complicações foi a doença vascular periférica (56,3%, p=0,003). Quanto às evoluções de enfermagem, 30 (29%) apresentavam registro do uso do cateter, e 28 (27%) relatavam o estado clínico do paciente após a sua retirada. Conclui-se que este estudo demonstrou que o índice de complicações ainda é alto quando relacionado ao BIA. Dentre os fatores de risco/comorbidades, a doença vascular periférica foi significativamente relacionada com complicações. Os registros dos enfermeiros foram subótimos.

DESCRITORES: estudos de coortes; balão intra-aórtico; cuidados de enfermagem

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INTRODUCTION

The use of intra-aortic balloon pump (IABP) has been increasing year by year, as a hemodynamic support resource for cardiac patients with left ventricular dysfunction. The use of this device is increasingly frequent in heart surgeries, as well as in hemodynamic units[1]. Its main goals include: greater oxygen flow to the myocardium, reduced workload of the left ventricle and improved cardiac output. Moreover, it increases coronary artery perfusion pressure during diastole[2].

Although, on the one hand, technological advances have benefited the increase in the safer use of this hemodynamic support device, some complications continue in patients submitted to this procedure. The most common complications include vascular injury, limb ischemia and infection. Other possible events include dissection or rupture of the aorta, due to balloon rupture, occurrence of clots or emboli or atheroma plaques, hemorrhages, a thrombocytopenia, besides cases of paraplegia, after IABP use[3].

In the context of IABP-resulting complications, a retrospective study in the Czech Republic reports that complications occur in 11.5% of patients, with limb ischemia as the most frequent (5.7%)[3]. A retrospective European study that involved 911 patients identified incidence levels of IABP-related vascular complications ranging between 8.7 and 20%. The same study also analyzed risk factors like hypertension, diabetes, earlier peripheral vascular disease, age, gender, smoking, obesity, duration of IABP therapy, presence of coronary artery disease, heart failure, mitral insufficiency, pulmonary arterial pressure and ejection fraction. In the same research, it was identified that, among risk factors, the strongest relation existed between peripheral heart disease and the presence of vascular complications[4]. A recent study analyzed IABP use in 662 patients and reported a 22% intra-hospital mortality rate, with 10.3% of other complications[1].

Another study carried out in North America, aimed at evidencing nursing implications in patients using IABP, demonstrated that nurses can detect vascular complications early through physical examination, monitoring patients' temperature, color, capillary perfusion and presence of distal pulses[5].

The lack of nursing studies in literature about the early detection and prevention of IABP-related complications and the non-existence of data about complications deriving from the use of this approach at the authors' place of work led to the development of this research.

OBJECTIVE

To identify complications in patients who used IABP and their relation with dwelling time, presence of risk factors/comorbidities and nursing records.

MATERIAL AND METHOD

This historical cohort, carried out in May and June 2006, assessed the files of adult patients who used IABP between 2001 and 2005, at a specialized cardiology hospital in Porto Alegre, Rio Grande do Sul. All patients ≥18 years of age who used clinical IABP or were submitted to surgery were included; patient files without any records on IABP usage time were excluded. An instrument was elaborated for this research to collect data on the following variables: age, gender, presence of comorbidities (diabetes mellitus, hypertension, history of peripheral vascular disease, severe coronary artery disease and smoking (>10 cigarettes/day). The remaining variables were related to the presence of the balloon catheter and included dwelling time (duration in hours) and insertion technique (percutaneous or dissection). Data on physical extremity examination and records on complications were taken from the medical and nursing evolutions; records on the presence of ischemia were taken from the evolutions that described the reduction in tissue perfusion and/or presence of cyanosis in the limb where the IABP is inserted. Vascular obstruction was defined according to team records on the presence of obstruction caused by embolism, thrombosis or gas.

This study was approved by the Ethics Committee at the research institution (approval number 3819/06 and, due to the impossibility to obtain the patients' informed consent, a term of commitment about the use of patient file data was used.

Statistical analysis

Statistical Package for Social Sciences 12.0 software was used for statistical analyses. Categorical

variables were expressed as total n and its relative percentages, and continuous variables were described as mean ± standard deviation and 25 and 75% percentiles, depending on their normal distribution or not. The chi-square test was used for categorical data comparisons. Quantitative variables were analyzed using Student's *t*, Spearman's and Wilcoxon's test, depending on whether they were parametric or not.

RESULTS

Clinical and demographic characteristics

This research included 104 files of patients submitted to IABP. Thirty files were excluded because they did not contain records on IABP placement time. The patients' mean age was 65±11 years, and 51.9% were men. The mean dwelling time in hours was 28 (12-57.5). Risk factors, comorbidities and use of anticoagulation therapy are shown in Table 1.

Table 1 – Description of demographic and clinical characteristics of patients (n=104) with IABP, 2001-2005, at a specialized cardiology hospital. Porto Alegre, RS, 2006

Clinical and demographic characteristics	n (%)
Age (years)*	64.9±10.7
Gender (male)	54 (52)
Median time with IABP in hours§	28 (12-57.5)
Peripheral vascular disease	16 (15.4)
Obesity	10 (9.6)
Diabetes	38 (36.5)
Systemic arterial hypertension	62 (59.6)
Smoking	45 (43.3)
Use of anticoagulation therapy	67 (64.4)

*mean ± standard deviation; § median and 25 and 75% percentiles.

IABP-related complications

Table 2 illustrates IABP-related complications. Twenty-six (25%) patients presented vascular complications like limb ischemia, followed by vascular obstruction. A small number of other complications were found, such as hemorrhage and infection. No cases of dissection and/or rupture of the aorta were found. The most severe complication was the amputation of an affected limb, which occurred in one case only.

Table 2 – Patient complications related to IABP use (n=26), 2001-2005, at a specialized cardiology hospital. Porto Alegre, RS, 2006

IABP-related complications	n (%)*
Ischemia	26 (25)
Vascular obstruction	13 (12.5)
Hemorrhage	2 (1.9)
Amputation	1 (1)
Infection	1 (1)

*Categorical variables expressed as n (%)

Complications related to presence of risk factors and/or comorbidities

Of all comorbidities under analysis, peripheral vascular disease was more frequently related with vascular complications and was found in 9 (34.6%) patients. Sixty-seven patients received anticoagulation therapy, of whom 42 (63%) displayed significantly less complications than the other 25 (37%) patients who did not receive this therapy (p<0.001). Moreover, men presented more complications than women (p=0.03). Mean IABP dwelling time was 28 hours (12-57.5), with patients who used the catheter for more than 37 hours (n=26) showing significantly more complications than patients with a median of 24 hours (p<0.05). The remaining variables produced no intergroup differences. These results are demonstrated in Table 3.

Table 3 – Vascular complications *versus* risk factors and/or comorbidities in IABP patients, 2001-2005, at a specialized cardiology hospital. Porto Alegre, RS, 2006

Comorbidity/risk factor	Vascular complications		P
	Yes (n=26)	No (n=78)	
Peripheral vascular disease	9 (34,6)	7 (9)	0,003
Obesity	1 (3,8)	9 (11,5)	0,20
Diabetes	10 (38,4)	28 (36)	0,80
Hypertension	15 (57,7)	47 (60,2)	0,80
Smoking	14 (53,8)	31 (39,8)	0,21
Anticoagulation	25 (96,2)	42 (53,8)	<0,001
Male gender	18 (69,3)	36 (46,2)	0,03
Usage time>37hours	26 (100)	- (-)	0,055

Variables expressed as n (%). *Chi-square.

Medical records on IABP use

The analysis of medical and nursing records showed that 68.3% contained some description of IABP use. Specifically for nursing records, of the 104

files under analysis, only 30 (28.8%) contained the evolution, describing the catheter use, and 28 (26.9%) reported on the patient's conditions after its removal. These data are demonstrated in Table 4.

Table 4 – Description of IABP patient files (n=104), 2001-2005, at a specialized cardiology hospital. Porto Alegre, RS, 2006

Criteria under analysis	n (%)
Physical limb exam	68 (65.4)
Evolution of complications by other professionals	27 (26)
Nursing evolution during use of IABP	30 (28.8)
Nursing evolution after use of IABP	28 (26.9)
Patients without records	33 (31.7)

*Categorical variables expressed as n (%).

DISCUSSION

Due to the high incidence of complications and the need for careful assessment by the IABP patient care team, the researchers investigated this reality at a specialized cardiology hospital. In total, 104 patient files were evaluated, of which 26 (25%) presented vascular complications – more than current literature data. All of these presented limb ischemia; only one presented a severe and irreversible lesion, including the need for amputation of the affected limb; no cases of aorta dissection of rupture were found. A retrospective cohort study that aimed to assess IABP-related vascular complications demonstrated 11.1% of complications, with ischemia as the most frequent vascular complication and women as the most affected gender[6]. An American study reported incidence levels ranging between 7.2 and 47% of vascular complications in cases of IABP use[5]. In 2000, a study of 1,174 patients who used IABP demonstrated 15% of complications. In this sample, 27% of patients had diabetes mellitus, 52% arterial hypertension and only 8%, peripheral vascular disease. The comparison between those research data and this more recent study showed that the present sample consisted of more severe patients in terms of the presence of comorbidities. The higher percentage of complications is also attributed to the fact that the place of study is a referral institution in cardiology and receives a large number of severe patients, which may entail a greater potential for the development of complications.

Among the risk factors under analysis, important relations were found between the appearance of vascular complications and peripheral vascular disease, IABP dwelling time and use of anticoagulation therapy or not. It was identified that 15.4% of patients suffered from peripheral vascular disease; 36% did not receive anticoagulation therapy; and dwelling time was longer in 100% of patients with complications. These findings underline current literature about the association between some comorbidities and the emergence of complications.

In this study, as opposed to other sources[6-7], female patients revealed fewer risks of complications than men. A study published in 2000 demonstrated, using multivariate analysis, that the female gender, peripheral vascular disease and high body mass index (BMI) were independent predictors for the appearance of complications[8]. This study, on the opposite, showed no correlation between obesity and female gender and the presence of complications, highlighting only peripheral vascular disease as the comorbidity that predicts adverse vascular events. Moreover, as data analysis was based on secondary sources, the records did not contain the patients' weight and height for the sake of BMI calculations, but merely records of obesity. European retrospective cohort studies carried out in 2000 and 2005 also emphasize the association between peripheral vascular disease and the use of anticoagulation therapy as risk factors for the occurrence of complications; opinions differ, however, on the relation between gender and adverse events[5-7].

In all 104 cases under analysis, catheter insertion was percutaneous. Other techniques, including artery exposure (dissection), have been appointed as predictors of further complications, such as dissection and rupture of the aorta, intense hemorrhages and patient death[8-9].

In this study, nursing records on the presence of IABP were unsatisfactory as to the description of perfusion conditions, skin color and presence of peripheral pulses in the limb the IABP was inserted in. No articles were found in literature that assessed nursing records and the use of IABP. However, articles in European, Asian and North American journals highlight the importance of nursing care for patients submitted to this mechanical support device. Research emphasizes that nurses should be trained as to the indications, benefits, risks and potential complications deriving from this approach. As a care strategy, an accurate physical examination of the extremity before,

during and after the catheter insertion is necessary[5,10]. The deficient nursing records may be related to the access of technical and administrative duties, as well as to the high number of patients under the professionals' responsibility, besides the fact that the institution has not fully implemented the nursing process and its routine. Despite a certain degree of consensus about the fact that the nursing process can contribute to a more autonomous and evidence-based practice, in nursing, few institutions actually adopt all of its steps[11]. To underline the importance of the nursing process, a systemic review carried out in 2007 identified 14 studies that proved the better quality of nursing documentation/assessments when the nursing diagnosis was applied[12]. The systemization of the nursing process supports the development of interdisciplinary and humanized care methodologies, serving as a work process. Care methods, independently of their denominations, represent one of the most important conquests in nursing care nowadays[13].

The team's actions in terms of constant and systematic patient assessment are highlighted as important factors for the early detection of complications and for planning interventions, as earlier studies indicate deficient recording of signs, symptoms and etiologies of nursing diagnoses[12]. The excessive number of patients and the whole complexity involved can often interfere in care, impairing the identification of complications in earlier stages. Patients with IABP are considered critical. Hence, nurses should be aware of potential problems and, through adequate assessment, identify patients at greater risk. Strategies like follow-up during catheter insertion and perfusion monitoring of patients' extremities and hemodynamic state, using a protocol with increasing assessment intervals, guarantee care[14]. In this context, training on the theme and recycling on care associated with the creation of specific nursing care protocols would constitute important strategies to guide professionals in their daily practice[15].

FINAL CONSIDERATIONS

The most frequent complications among IABP patients were vascular, including limb ischemia (25%) and vascular obstruction (12.5%). When related to catheter dwelling time, it was evidenced that patients who used it for more than 37 hours presented significantly more complications that patients with a median usage time of 24 hours. As for risk factors associated with complications, higher incidence levels were found in male patients and with a history of peripheral vascular disease. With regard to nursing records, only 28.8% described the use of IABP.

Despite the large technological evolution in this area, complication rates remain high, mainly of vascular complications. Nevertheless, the improvement in cardiac output as a result of this treatment is undeniable. In this scenario, the relation between the risks and benefits of the method should be assessed against the background of factors associated with possible future complications.

The main risks for IABP patients are bleeding, balloon rupture, infection and skin breakdown. The occurrence of these complications can be minimized by periodical clinical assessment, in addition to the monitoring of laboratory results for hematocrit and hemoglobin, platelet and coagulation markers. Besides, back, flank or abdominal pain complaints should be assessed and recorded, and distal pulse characteristics should be observed. Control of body temperature, as well as redness, warmth, swelling or drainage at the insertion site is mandatory. Finally, interventions to reduce pressure areas and hydration and nutrition control surveillance are important aspects in the daily assessment of these patients[15]. Some other strategies, such as the full implantation of the nursing process and the use of pulse evaluation protocols can add benefits to this treatment.

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