Validation of a protocol to assist patients with intra-aortic balloon*

Validação de protocolo paraassistênciaa pacientes com balão intra-aórtico

Validación de un protocolo para la asistencia a pacientes con balón intraaórtico

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ABSTRACT

Objective: To develop a protocol of care for patients with Intra-Aortic Balloon and validate the content of this protocol.**Methods:** Study of quantitative and descriptive approach. The methodology followed three steps: development of the instrument; content validity and reliability verification of the protocol for the analysis of agreement between specialists with greater experience. The study included 48 specialists, including physicians and nurses experienced in patient care in use of balloon. Items considered valid achieved at least 75% of consensus before the analysis of agreement between evaluators. **Results:** We evaluated 36 items, of these, 20 were considered valid. The reliability was also verified, using consistency of the responses of more experienced evaluators. Among the items submitted to new statistical analysis by these evaluators, only two were considered valid. **Conclusion:** Based on the content validation, a protocol with 22 items concerning patient care without the use of intra-aortic balloon was developed.
Keywords: Intra-aortic balloon pumping/nursing; Protocols; Patient care; Counterpulsation; Assisted circulation; Heart failure; Validation studies; Nursing care

RESUMO

Objetivos: Elaborar um protocolo de cuidados a pacientes com Balão Intra Aórtico e validar o conteúdo desse protocolo. **Métodos:** Estudo de abordagem quantitativa, descritivo. A trajetória metodológica seguiu três etapas: elaboração do instrumento; validação do conteúdo e verificação da confiabilidade do protocolo pela análise de concordância entre peritos com maior tempo de experiência. Participaram do estudo 48 peritos, entre médicos e enfermeiros, experientes em assistência ao paciente em uso do balão. Os itens considerados válidos obtiveram consenso mínimo de 75% perante a análise de concordância entre os avaliadores. **Resultados:** Foram avaliados 36 itens, destes, 20 foram considerados válidos. Verificou-se também a confiabilidade, utilizando a congruência das respostas dos avaliadores mais experientes. Dos itens submetidos à nova análise estatística por esses avaliadores, apenas dois foram considerados válidos. **Conclusão:** Com base na validação do conteúdo, elaborou-se um protocolo com 22 itens referentes aos cuidados a paciente sem uso do Balão Intra-Aórtico.
Descritores: Balão intra-aportico/enfermagem; Protocolos; Assistência ao paciente; Contrapulsação; Circulação assistida; Insuficiência cardíaca; Estudos de validação; Cuidados de enfermagem

RESUMEN

Objetivos: Elaborar un protocolo de cuidados a pacientes con Balón Intraaórtico y validar el contenido de ese protocolo. **Métodos:** Estudio de abordaje cuantitativo, descriptivo. La trayectoria metodológica siguió tres etapas: elaboración del instrumento; validación del contenido y verificación de la confiabilidad del protocolo por el análisis de concordancia entre peritos con mayor tiempo de experiencia. Participaron en el estudio 48 peritos, entre médicos y enfermeros, con experiencia en asistencia al paciente en uso del balón. Los items considerados válidos obtuvieron consenso mínimo del 75% frente al análisis de concordancia entre los evaluadores. **Resultados:** Fueron evaluados 36 items, de éstos, 20 fueron considerados válidos. Se verificó también la confiabilidad, utilizando la congruencia de las respuestas de los evaluadores más experientes. De los items sometidos al nuevo análisis estadístico por esos evaluadores, apenas dos se considerarons válidos. **Conclusión:** Con base en la validación del contenido, se elaboró un protocolo con 22 items referentes a los cuidados al paciente sin uso del Balón Intraaórtico.
Descriptores: Contrapulsador intraaórtico/enfermería; Protocolos; Atención al paciente; Contrapulsación; Circulación asistida; Insuficiencia cardíaca; Estudios de validación; Atención de enfermería

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INTRODUCTION

The behavioral changes, particularly, by the processes of industrialization and urbanization, generated changes related to eating habits, increased physical inactivity, obesity and smoking[1,2].

These changes are responsible for the increased rates of cardiovascular disease, among which, the heart failure (HF), recognized as an issue of relevance for public health, particularly in developed countries[2,3].

The choice of treatment of advanced HF with therapeutics improvements and early intervention aims to provide a better quality of life, reduce hospitalizations and improve survival of patients[3-7]. However, considering that a significant number of patients evolves for the most advanced and irreversible stage of the disease, even under medication optimization and intensive treatment, it requires referral to heart transplantation[8,9]. But, due to scarce number of donors, unfortunately, many patients die while waiting for atransplantat[9,10].

However, for patients with HF and hemodynamic unstable,sometimes, hospitalization is required with the primary objective of optimizing their clinical condition. This optimization is performed by inotropic drugs and application of mechanical circulatory support (MCS). It is noteworthy that MCS can be used as a "bridge" to heart transplantation[11,12].

MCS may be divided, according to the use of two types of devices: Cardiac replacement (total artificial heart) and ventricular assist devices (VAD). These can be subdivided into assistance in series by counterpulsation (intra-aortic ballon – IAB) and by assistance in parallel – implantable artificial ventricles: Heart-mateandNovacoror paracorporealInCor, Thoratecand BertinHeart[11-13].

VAD has the property to recover partially or all cardiac output and, thereby, ensure systemic perfusion. So,one of the most used devices with the intention of assisting or restore coronary blood flow is the IAB[11,12,14].

However, complications from its use can be related to several factors, such as infections, limb ischemia, the balloon rupture, bleeding, paraplegia (rare) and abdominal pain that can be caused by mesenteric artery occlusion[11,15,16].

In this context, the extensive knowledge of the patient allows planning therapeutic interventions to provide quality care. However, a way to address the care provided to clients is the validation of a protocol of care.

For this study, we considered the validation of content for consisting in the convergent opinion of the evaluators, emphasizing the need for consensus among the group of participants[17]. This tool is useful and efficient in guiding patient care, and is based in prognosis of care as in the adjustment between human, material and physical resources.

The theoretical framework obtained showed some important elements in the construction of variables addressed at assisting the patient with HF presenting hemodynamic instability and need for mechanical circulatory assistance by IAB. However, the lack of studies with consensual approach in the standardization of care were not satisfactory, thus, this study aimed to develop and validate the contents of a protocol of care for patients with Intra-Aortic Balloon.

METHODS

Descriptive study, with a quantitative approach developed a protocol of care for patients with IAB. The methodology followed three steps: preparation of data collection instrument; content validation and verification of the reliability of the instrument for the analysis of agreement among specialists with greater time experience.

In order todevelop this instrument, a systematic search of the literature was done in order to investigate the care provided to patients with IAB[11-14,16,18,19] and referring the research protocolto Research Ethics Committee of the Federal Universityde Sao Paulo with approved protocol under No. 1.484/08.

Aiming to refine the instrument on the scope, clarity, relevance and configuration, as well as whether the proposed items contemplated the parameters established forIABcare, an evaluation was performed by two physicians and three nurses, given some selection criteria for evaluators, such as medical specialization in cardiology or intensive care.

After the preparation and refinement of the instrument, we began the process of recruiting specialist professionals for the final evaluation.

Professionals from public and private health care facilities of Sao Paulo were contacted by the researcher that, in total, delivered 65 instruments with concomitant clarification of objectives, purpose and fulfillment of the research, between December 2008 and May 2009 and established the deadline of 30 days for analysis and its return. Therefore, the sample is constituted by 48 evaluators, including 20 physicians and 28 nurses.

According to the literature, there is no consensus on the quantitative portion of the evaluators group to validate the items of an instrument, however, the number of specialists available will depend on the available sample that the researcher can contact[20,21].

Thus, the selection of the sample of professionals who participated in this research occurred by "snowball

sampling or networkingsampling"[17], which consists onthe requesting for the first subjects from the sample to indicate or recommend other individuals who meet the selection criteria for the study.

The following parameters for the selection of evaluators were established: bea specialist in Cardiology and Intensive Care, with a minimum time of experience of one year working with the proposed theme and scientific production on the topic in recent years.

To develop the protocol of care for patients undergoing MCS with IAB, were only considered relevant the evaluationsopinions converging favorable with a minimum level of 75% based on statistical analysis. This agreement index was basedin other validation studies[20,21].

The verification of reliability is an important factor in indicating the quality of an instrument[17]. Thus, the choice of a model to verify the reliability of the instrument was used by the congruence of content responses to understand that consistency comes from the agreement between evaluators.

The instrument variables that did not reach the minimum value level (75%) and presented different responses to the questions were submitted to a new descriptive statistical analysis that considered the opinion of 15 professionals with longer time of experience,over 8 years in the Intensive Care Unit. At this step, it was checked which response had the highest percentage of agreement among evaluators,so that these issues could also be validated.

We selected some answers (in pairs) to determine the association between them; the statistical test of Chi-square (c^2) or Fisher's exact test was applied and the significance level of 5% wasobserved.However, only two variables showed favorable rates.

RESULTS

We evaluated 36 items directed to patient care in use of the IAB, however, the first 20 were considered relevant by presenting converged opinions 48 (100%) evaluators with the minimum level of agreement in favor of 75% (Table 1).

Table 1. Findings of the evaluators on the relevant items of the protocol of care for patients with intra-aortic balloon. Sao Paulo / 2009

Variables	Yes n(%)	No n(%)	No Answer n(%)	Total n(%)
Clarify the patient about the risk-benefit of IAB	46(95.8)	2(4.2)	0(0.0)	48(100.0)
Clarify the family members about the risk-benefit of IAB	48(100.0)	0(0.0)	0(0.0)	48(100.0)
Scrubbing into perform the insertion of the IAB	47(97.9)	1(2.1)	0(0.0)	48(100.0)
Putting heparin in the solution which fills the transducer system	39(81.3)	9(18.7)	0(0.0)	48(100.0)
Use solution of alcoholic 2% chlorhexidine to clean the insertion site of the IAB	41(85.4)	4(8.4)	3(6.2)	48(100.0)
Preferably install the catheter into the femoral artery and restrict limb with the catheter insertion	42(87.5)	4(8.3)	2(4.2)	48(100.0)
Keep patient in supine position	43(89.6)	5(10.4)	0(0.0)	48(100.0)
Assess the position of the catheter on chest radiography and perform clinical evaluation of the catheter insertion limb	48(100.0)	0(0.0)	0(0.0)	48 (100.0)
Assess with Doppler ultrasoundthe catheter insertion in the limb.	46(95.8)	2(4.2)	0(0.0)	48(100.0)
Indicate anticoagulation with subcutaneous heparin	40(83.3)	8(16.7)	0(0.0)	48(100.0)
Assess coagulation – INR, aPTT and platelets and perform apressure dressing after catheter removal	47(97.9)	1(2.1)	0(0.0)	48(100.0)
Make the dressing change common site of catheter insertion and pressure dressing after 24 hours	44(91.6)	2(4.2)	2(4.2)	48(100.0)
Constantly monitor the heart rate	45(93.8)	3(6.2)	0(0.0)	48(100.0)
Monitor the functionality of the device (console) of IAB	48(100.0)	0(0.0)	0(0.0)	48(100.0)
Monitor the amount of helium gas	47(97.9)	1(2.1)	0(0.0)	48(100.0)
Removal of the balloon catheter by medical professional	42(87.5)	6(12.5)	0(0.0)	48(100.0)
Weaned from circulatory assistance and the counterpulsation should be progressively reduced1:1, 1:2 to 1:3, associated to hemodynamic stabilization and gradual progressive reduction of drugs*	13(86.7)	2(13.3)	0(0.0)	15(100.0)
The pressure after removal of the catheter should be manual*	12(80.0)	3(20.0)	0(0.0)	15(100.0)

*The Fisher exact test for variables submitted to new statistical analysis by 15 (100%) of the evaluators with greater experience showed a p-value <0.05.
IAB, intra-aortic balloon; INR, International Normalized Ratio; aPTT, partial thromboplastin time;HR, heart rate.

Based on the evaluation of items relating to the care of patient without usingIAB and content validation of the items that had at least 75% favorable level, we drew up a protocol with 22 itemsdescribed in Box 1.

Box 1. Protocol of Care of Patients with Intra-Aortic Balloon

Action	Justificative	Action	Justificative
1. Clarify the patient about the risk-benefit of intra-aortic balloon (IAB).	Better preparation for initiation of therapy in order to reduce anxiety and provide a humanized care.	12. Indicate anticoagulant heparin subcutaneously (SC) -enoxoparin (medical management).	Prevent the formation of thrombus.
2.Clarify the family members about the risk-benefit of IAB.	Communication and education Efficient of patients and families, about the limitations of mobility, possible complications and the area where the catheter will be inserted.	13. Assess the coagulation – InternationalNormalized Ratio (INR), partial thromboplastin time (aPTT) and platelets every 6 hours.	The prolonged counterpulsation can cause hemolysis due to the use of anticoagulants.
3.Scrub in for insertion of the IAB.	Precaution of infection during catheter insertion, using caps, gowns and masks, and sterile gloves.	14. Make the dressing change common site of catheter insertion every 24 hours.	Check the catheter insertion site for signs of infection and hematoma.
4. Putting heparin in the solution which fills the transducer system.	Prevent clogging of the system.	15. Constantly monitor the heart rate (HR).	Very fast HR can impair the process of synchronizing the balloon with the cardiac cycle and provide counterpulsation ineffective.
5. Using solution of 2% chlorhexidine for cleansing the insertion site of IAB.	It has antibacterial activity to grampositive and gram negative, with a residual effect of 6 to 8 hours, being quite effective in a single application.	16. Monitor the functionality of the device (console) of the IAB.	Constant assessment and systematic operation of the console, in relation to possible problems in the monitor, catheter obstruction or collapse and gas leaks.
6. Install catheter preferably in femoral artery (medical management).	For the insertion of the balloon catheter, the arterial caliber must be enough to accommodate it and maintain distal flow of the limb.	17. Monitor the amount of helium gas, observing the indication sensor that records low volume on the monitor console.	Observation of the need to hold the gas exchange shaftof the equipment.
7. Keep the patient in supine position after insertion of the catheter.	Prevention of breakage or migration of the catheter.	18. Weaned afterhemodynamic stabilization, thegradual decrease of the drugs, and the reduction of the mandatory cycles of counterpulsation1:1 to 1:3.	Evaluate each item before IABweaned.
8. Restrict limb with catheter insertion.	Avoid bending the limb in order to prevent hematomas or blood flow obstruction to the limb.	19. Removing the balloon catheter by the physician.	During removal of the catheter complications may occur as limb ischemia or pulmonary embolism by displacement of possible thrombus.
9. Assess the position of the catheter in the chest radiograph every 12 hours.	The performance of the IAB can be related to its positioning.	20. Perform manual pressure after catheter removal.	For prevention of bleeding.
10. Perform a clinical assessment on the limb of catheter insertion every 6h.	Considering risk of limb ischemia, as evidence of poor peripheral perfusion and arterial insufficiency.	21. Perform pressure dressing after catheter removal.	To prevent bleeding or hematomas.
11. Evaluating the limb of the catheter insertion withDoppler Ultrasound every 12 hours.	Determining the presence or absence of distal pulses as the tibial and dorsalispedis.	22.Replace the pressure dressing after 24 hours.	In order to evaluate the site.

DISCUSSION

The literature provides data to establish care in various situations of the patient with IAB. Based on this information, we identified the care analyzed in this study.

Aiming to reduce anxiety and provide a humanized care, it was considered appropriate to clarify patients and their families about the risks and benefits of IAB. These items support the scientific literature, when it describes the importance of communication and education regarding mobility limitations and possible complications of the catheter[18].

The importance of professional scrub in to perform the insertion of IAB, obtained a high degree of consensus among evaluators. This data reference the findings in the literature[19,22] on the precaution of infection during insertion of catheters using the appropriate garment.

Favorable agreement regarding the use of heparin solution in the transducer was presented. However, we did not find any studies that explored this issue.

Chlorhexidinegluconate at concentrations of 2% proved to be a suitable antiseptic solution for achieving antisepsis at the site where the arterial catheterwas inserted. Regarding the theoretical framework, the solution has antibacterial activity for grampositive and gramnegative, with a residual effect of 6 to 8 hours[19].

The femoral artery was the site of choice for insertion of the balloon catheter, to be sufficiently large caliber to accommodate it and maintain distal limb flow. However, the catheter can be inserted into other arteries such as the iliac, left subclavian artery and ascending aorta[12].

The item relating to the maintenance of limb restriction, where the catheter is inserted, showed favorable rate between evaluators. This care of avoiding hip flexion appears to be useful in preventing hematomas or preventinglimb blood flow obstruction.

The analysis to evaluate the relevance in keeping the patient in the supine position obtained anagrement rate of 89% between the evaluators. On the other hand, studies suggest that the head-of-bed should be elevated to 30°[18].

The verification of the catheter position in the chest radiograph obtained a favorable agreementrate. The balloon catheter is flexible and should be positioned close to the emergence of the left subclavian artery and above the renal arteries. Observation regarding the balloon end, which is radiopaque until a distal position to the aortic root[11], its observation being important every 12 hours. However, one study showed that the aortic rootmay not be suitable to evaluate catheter position, due to the large shadow that this exerts on the radiograph,thereforethe carina, due to its clearer anatomy may be a practical way to evaluate the position of the balloon[23].

The clinical assessment and Doppler ultrasound evaluation of the limb inserted, in order to avoid risk of thrombosis or arterial occlusion, showed predominance and should be performed at least every 12 hours. The limb ischemia is considered the most frequent complication in patients using the IAB[19]. The main reasons are distal thrombusof arterial injury during catheter insertion and venous thromboembolism (VTE)[16,18,24]. Doppler ultrasound examination will determine the presence or absence of distal pulses difficult to be palpated, especially the tibial and dorsalispedis[18].

In this context, the verification of femoral circulation, popliteal, tibial and dorsalispedis should be performed every 15 minutes during the first hour, every 30 minutes, in the second hour; then, every 2 hours and every 4 hours, until the removal of the catheter[18].

A study evaluating the relationship of the duration of the complications presented by the use of IAB showed a lower rate of complications in a group of patients with shorter duration of therapy. The group with longer period, despite the low incidence of complications, presented limb ischemia as the most observed and also with increased risk among women and the elderly[16].

The relevance of using heparin SC (enoxoparin) as preventing complications, showed high rate of agreement between evaluators, especially the presence and movement of the catheter in the intimal layer of the artery with the endothelium that may favor thrombosis or laceration[12,24]. Studies relating patients with VAD and reduced mobility indicate anticoagulation with low molecular weight heparin for prophylaxis of venous thromboembolism[11-12,24].

The item on the evaluation of coagulation test, as the International Normalized Ratio (INR), the partial thromboplastin time (aPTT) and platelets obtained a high level of agreement. One of the complications of the patient to use the IAB is bleeding. Thebleeding should be monitored, evaluating catheters, drains, probes and guide the degree of anticoagulation by the results of the coagulation every 6 hours[24,25].

When analyzing the item time of change of common dressing, with gauze and porous adhesive, there was consensus among evaluators for the dressing to be changed every 24 hours. These data, therefore,relate tothe findings in the literature prescribing the dressing changes between 24 to48 hours[19].

Regarding the hemodynamic parameters, only heart rate (HR) obtained agreement between evaluators. The heart rate of the patient, if too fast, can impair the process of synchronizing the balloon with the cardiac cycle and provide ineffective counterpulsation, thus justifying the relevance of the constant monitoring of this parameter.

The observation of hemodynamic conditions is a constant process, since the importance of this observation is not restricted only in evaluating the clinical outcome, but also about the right moment to weaned from circulatory support.

As to item relevance in monitoring the correct functionality of the IAB and monitor the amount of helium gas, yielded aagreement rate of almost 100%. It is understood that the console is the device responsible for inflating and deflating the IAB, using helium gas. This cycle can be synchronized with the electrocardiogram tracing the patient's heart rhythm or in syncing with the trace of systemic blood pressure[11]. Faced with this, the nursing team must constantly verify the data provided by the console monitor for early detection of potential problems regarding the functionality of the equipment.

Regarding the important parameters weaned fromI-AB, no item presented isolated consensus of 75%. While, in the reassessment with more experienced specialists, the question that all items must be evaluated before weanedfromIAB, presented favorable rate of 87%. These data are similar to the literature, when referencing that weaned from circulatory support, the counterpulsation should be progressively reduced[25].

During IAB removal, complications can occur such as limb ischemia or arterial thrombosis displacement of possible thrombus[24]. For these reasons, the IABremoval must be performed with great care and caution. However, there was harmony between the evaluators for the physician to remove the balloon catheter. There

are reports in the literature that catheter removal is an action exclusively performed by the physician[25].

Related to the type of local pressure after catheter removal, manual pressure showed 80% consensus after reevaluation with the more experienced specialists[25].

The agreement index of the evaluators for the items related to the type and time for performing dressing change after catheter removal was nearly 100% for the type of pressure dressing and changing every 24 hours. Result that resembles the findings in the literature, to reinforce that the pressure dressing should be done and that the limb should stay still for 6 hours after catheter removal[25].

The protocol promotes a scientific framework for the coordination of care, having as main features, the flexibility and constant updating of knowledge based in evidenced and scientifically substantiated new situations[26].

Therefore, the foundation of the scientific literature and clinical practice of professionals have emerged to create a protocol of care to the patient using IAB.

CONCLUSION

From the content validation, a protocol was developedwith twenty-two items relating to the care of patients using intra-aortic balloon.

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