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Elaboration and validation of a protocol for the care of patients with COVID-19 in hemodialysis centers

Elaboração e validação de protocolo para atendimento de pacientes com COVID-19 em centros de hemodiálise

Elaboración y validación de protocolo de atención al paciente con COVID-19 en centros de hemodiálisis

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ABSTRACT

Objective: To describe the elaboration and validation of a protocol for the care of suspected patients with Coronavirus Disease-19 (COVID-19) undergoing hemodialysis.

Method: A methodological study conducted from March to August 2020 at a hospital in southern Brazil. The study involved situational diagnosis, literature review, protocol elaboration and content validation (scope, clarity and relevance). Ten professionals from the multidisciplinary team with experience in caring for patients with kidney disease and an official Nursing supervisory body participated in the validation. 100% consensus was reached among the experts.

Results: The following were elaborated: "Flow of patient care consisting of six stages" and "Management plan for dialysis centers". The validation allowed improving and refining the content, complying with the precepts of health standards, safety and clinical guidelines.

Final considerations: The elaboration and validation of the protocol can standardize and guide the clinical practice, promoting continuity and safety in care, and can be used in other centers.

Keywords: Renal dialysis. Clinical protocols. Coronavirus infections. Validation study. Patient safety.

RESUMO

Objetivo: Descrever a elaboração e validação de um protocolo para atendimento de pacientes suspeitos ou com *Coronavirus Disease-19* (COVID-19) em hemodiálise.

Método: Estudo metodológico conduzido de março a agosto/2020 em hospital do sul do Brasil. O estudo envolveu diagnóstico situacional, revisão da literatura, elaboração do protocolo e validação de conteúdo (abrangência, clareza e pertinência). Participaram da validação dez profissionais da equipe multidisciplinar com experiência no atendimento de pacientes com doença renal e um órgão oficial fiscalizatório de enfermagem. Obteve-se 100% de consenso entre os especialistas.

Resultados: Foram elaborados: "Fluxo de atendimento para pacientes constituído de seis "etapas" e "Plano gerencial para centros de diálise". A validação permitiu aprimorar e refinar o conteúdo atendendo preceitos de normas sanitárias, segurança e diretrizes clínicas.

Considerações finais: A elaboração e validação do protocolo podem padronizar e nortear a prática clínica, promovendo a continuidade e a segurança no cuidado, podendo ser utilizado em outros centros.

Palavras-chave: Diálise renal. Protocolos clínicos. Infecções por coronavírus. Estudo de validação. Segurança do paciente.

RESUMEN

Objetivo: Describir la elaboración y validación de un protocolo para la atención de pacientes sospechosos o con *Coronavirus Disease-19* (COVID-19) en hemodiálisis.

Método: estudio metodológico realizado de marzo a agosto / 2020 en un hospital del sur de Brasil. El estudio incluyó diagnóstico situacional, revisión de la literatura, elaboración de protocolos y validación de contenido (alcance, claridad y relevancia). En la validación participaron diez profesionales del equipo multidisciplinar con experiencia en el cuidado de pacientes con enfermedad renal y un órgano de control oficial de enfermería. Se alcanzó un consenso del 100% entre los expertos.

Resultados: Fueron elaboraron: "Flujo de atención al paciente en seis etapas" y "Plan de gestión para centros de diálisis". La validación permitió mejorar y afinar el contenido, cumpliendo con los preceptos de las normas de salud, seguridad y guías clínicas.

Consideraciones finales: La elaboración y validación del protocolo puede estandarizar y orientar la práctica clínica, promoviendo la continuidad y seguridad en la atención, pudiendo ser utilizado en otros centros.

Palabras clave: Diálisis renal. Protocolos clínicos. Infecciones por coronavirus. Estudio de validación. Seguridad del paciente.

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INTRODUCTION

In 2019, the World Health Organization identified a new beta coronavirus called *Severe Acute Respiratory Syndrome Coronavirus* 2 (SARS-CoV-2); this virus is the cause of COVID-19 that generated a pandemic in 2020[1]. Currently, some aspects of this disease are already identified and it is known that, in severe cases, the patients can present an acute kidney disease. It is estimated that from 20% to 40% of the patients admitted due to COVID-19 to intensive care centers present renal dysfunction requiring some type of dialysis. This situation is considered a marker for disease severity and a negative prognostic factor for mortality[2].

The occurrence of COVID-19 in patients with chronic kidney disease undergoing hemodialysis is scarcely known. However, it is known that this population is at risk, as they are immunosuppressed patients with various comorbidities, such as systemic arterial hypertension, diabetes, heart disease and impaired respiratory capacity. Added to this, they have frequent exposure to the hospital environment for conduction of the therapy, as well as due to the commutes. When infected with the SARS-CoV-2 virus, these patients interrupt the isolation circuit, both at their homes and in the dialysis center[3].

In the current COVID-19 pandemic context, the health services need to adapt quickly due to the increased demand for care and new knowledge about the disease. This fact requires organization from the care team to attend to all aspects involved, such as the establishment of safe practices, team engagement and users' education[4,5]. Thus, the development of care protocols can assist in care management and in decision-making, as they are based on the best scientific evidence available.

In this context, despite the risk of contamination, the particularities of the patient with kidney disease and the greater demand, it is indispensable that dialysis centers organize themselves to assist the patients. Given this scenario, the research question of this study is "What stages in a protocol are necessary to establish safe and effective hemodialysis care for patients with suspected or confirmed infection by the SARS-CoV-2 virus"? Thus, the objective of this research is to describe the development and validation of a protocol for the care of patients with suspected or confirmed infection by COVID-19 undergoing hemodialysis.

METHOD

This is a methodological study developed in four stages. It was initiated with a situational diagnosis, followed by a search for scientific literature on the topic, elaboration of the protocol and subsequent content validation by experts. The research was conducted from March to August 2020 in a hemodialysis unit of a large-size university hospital in southern Brazil that is a reference in the care of patients with kidney disease and also for the treatment of patients with COVID-19. This sector has 21 beds, capacity for 66 sessions/day and a mean of 1,100 sessions/month of outpatient and in-hospital cases.

The situational diagnosis was carried out by the nurses of the hemodialysis unit, seeking to identify the needs of the patients and of the care team, aiming at continuity of care for suspected or confirmed COVID-19 cases. This process involved seven meetings in order to discuss and establish the particularities of the disease in question and its relationship with the hemodialysis care process. Aspects that needed to be improved were listed, such as knowledge about transmission of the disease, infection control, patient/care team safety and risk/severity of the renal patient.

Afterwards, a review of the scientific literature was carried out following the method proposed by the National Collaboration Center for Methods and Tools[6], which consists of the search for evidence according to a six-level pyramid (6S), starting with more synthesized evidence (clinical guidelines and systematic reviews) up to less synthesized evidence (original studies). The search for evidence was performed using the PubMed, Cochrane and Google Scholar databases, as well as documents from national and international health agencies. Publications from December 2019 to August 2020 were selected using the following terms: *"Coronaviridae Infections"* [MeSH] and *"Kidney Failure, Chronic"* [MeSH] or "Hemodialysis Units, Hospital" [MeSH] or "Renal Dialysis" [MeSH] and "*Disease Transmission, Infectious*" [MeSH] or "*Communicable Disease Control*" [MeSH]. The quality of the scientific evidence was determined using the Appraisal of Guidelines of Research & Evaluation (AGREE II) tool[7].

Subsequently, a work group consisting of 12 nurses specialized in Nephrology and working in the area of dialysis was organized to prepare the protocol. Thematic subdivisions of the protocol to be written by pairs of nurses were established. Afterwards, weekly meetings were held with the work group to evaluate and improve the material developed in the light of the daily care experience and the scientific evidence selected.

For the protocol content validation stage, the inclusion criteria of the specialists were to have at least ten years of experience as a professional in hemodialysis and to be on the front line during the pandemic. Validation allows achieving collective opinion or agreement among experts regarding a specific phenomenon and aims at defining standards of practice[8]. The sample was selected for convenience, constituting

a group of specialists comprised by a nephrologist, three nursing technicians, four nurses with a specialization in the area of Nephrology, two university professors of the Nursing course with management experience in the area and an official Nursing inspection body. The specialists were asked to carefully evaluate the text as to the scope, clarity, layout and relevance of the protocol items. The validation process was guided by the following questions: Does it meet health and safety standards considering the particularities of hemodialysis assistance? Does it provide an understanding of the problem studied with scientific grounds? Does it have the potential to be used as a care guide? Does the language and layout allow for proper understanding of the content?

Content validation took place after performing six discussion rounds, being refined until the content was considered appropriate and feasible to be implemented in the clinical practice, obtaining 100% consensus among the experts. Subsequently, an external assessment by an official Nursing regulatory body was also requested in order to ensure the ethical and legal care-related aspects.

The specialists' participation was voluntary and occurred in person and online, which enabled improvement of the protocol for the care of hemodialysis patients. Anonymity was guaranteed and the project was approved by the institution's research ethics committee under Certificate of Presentation of Ethical Appreciation (*Certificado de Apresentação de Apreciação Ética*, CAAE) 2729218300005327.

RESULTS

The study allowed developing and validating a protocol for the care of patients with COVID-19 in hemodialysis centers. The initial situational diagnosis gave rise to the foundations for the construction of the protocol which, together with the results of the scientific evidence, culminated in the elaboration of a patient care flow and a management plan for dialysis units. The review of the scientific literature resulted in 13 articles, which included the clinical guidelines of national and international health agencies that deal with the theme of the study and other information necessary for the elaboration of the protocol (Figure 1).

One of the results of this study was the elaboration of the "Flow of care for patients with suspected or confirmed infection by COVID-19 undergoing hemodialysis", which contemplated specific aspects of the hemodialysis therapy for patient care, consisting of six stages: pre-hemodialysis screening, referral of suspected cases, transportation and allocation to dialysis rooms, infection control measures in the environment and guidance on the use of personal protective equipment (Figure 2).

Due to the dynamic nature of the pandemic, daily guidelines to the teams and patients were necessary during preliminary application of the protocol. Thus, a guiding plan was provided to define the care actions to be performed by the patients, relatives and caregivers. To this end, the care teams received instructions during shift changes or meetings on online platforms. The patients' education in health, on the other hand, took place in conversation circles with small groups, in shifts and in the hemodialysis waiting rooms, which facilitated their understanding regarding changes in relation to the epidemiological recommendations. Thus, the "Managerial Plan for hemodialysis centers in the care of COVID-19 cases" was prepared covering aspects such as guidance for users of the health service, contingency plan, reports on the health conditions of patients and of the staff, and staffing (Figure 3).

Validation allowed refining the content created, with improvement in some aspects, as it involved specialists with knowledge in the area and able to assess the scope, clarity, adequacy, layout and relevance of each item in the protocol. It also emphasizes the fact that it is being implemented as it was being elaborated, taking into account the pandemic.

DISCUSSION

Due to the lack of immunization for the SARS-CoV-2 infection to the present day, measures focused on identifying suspected cases and their early isolation were very important. In hemodialysis, the screening of patients performed before each session was a fundamental part of this process and helped to control spread of the pandemic. The literature emphasizes that the implementation of this stage involves adaptation of the physical space and training of the health team, requiring the professionals to know the signs and symptoms of the disease and to maintain a vigilant behavior in order to identify suspected cases[15].

In addition to that, standardization of care in the hemodialysis unit, regulated by norms and protocols, allows identifying potential contamination sources to which the patient is exposed and provides confidence in decision-making by the professionals. Thus, health organizations emphasize the importance of considering the care stages that involve transit and permanence of contaminated patients inside the hemodialysis center. In this case, the characteristics of each locus, hospital environment or outpatient clinic must be considered, in order to establish the best flow for transit of the patients. Dialysis in isolation rooms for these patients is mandatory and all recommended infection control measures must be adopted. The literature recommends that control of the care activities and cleaning of the environment prevent

Health Agency	Clinical Guideline
World Health Organization (WHO)	Infection prevention and control during health care when COVID-19 is suspected.[7]
Centers for Disease Control and Prevention (CDC)	Interim Additional Guidance for Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities.[8]
American Society of Nephrology (ASN)	Information for Screening and Management of COVID-19 in the Outpatient Dialysis Facility.[9]
International Society Nephrology (ISN)	Recommendations for the Novel Coronavirus 2019 Epidemic.[10]
Brazilian Ministry of Health	*Diretrizes para Diagnóstico e Tratamento da COVID-19.*[1]
National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA)	Technical Note GVIMS/GGTES/ANVISA No. 04/2020. *Orientações Para Serviços De Saúde: Medidas De Prevenção E Controle Que Devem Ser Adotadas Durante A Assistência Aos Casos Suspeitos Ou Confirmados De Infecção Pelo Novo Coronavírus (SARS-CoV-2).*[11]
National Health Surveillance Agency (ANVISA)	Technical Note GVIMS/GGTES/ANVISA No. 07/2020. *Orientações para Prevenção da Transmissão de COVID-19 dentro dos Serviços de Saúde.*[12]
Brazilian Society of Nephrology (*Sociedade Brasileira de Nefrologia*, SBN)	*Recomendações de Boas Práticas da Sociedade Brasileira de Nefrologia às Unidades de Diálise em relação a Epidemia do novo Coronavírus (COVID-19).*[13]
National Institute for Health and Care Excellence (NICE).	COVID-19 rapid guideline: dialysis service delivery.[14]
Italian Society of Nephrology (*Società Italiana Nefrologia*, SIN)	*Raccomandazioni per l'assistenza infermieristica al paziente dializzato e trapiantato.*[15]
Spanish Society of Nephrology (*Sociedad Espanola de Nefrologia*, SEN)	*Recomendaciones para el manejo, prevención y control de COVID-19 en Unidades de Diálisis*.[3]
Australian and New Zealand Society Nephrology (ANZA).	ANZSN and RSA COVID-19 Workforce Preparedness Checklist - Monitoring and Managing Health Care Workers (HCWs).[16]
Canadian Society of Nephrology (CSN).	Novel Coronavirus (COVID-19) for Hemodialysis Outpatients.[17]

Figure 1 – Scientific evidence for the care of COVID-19 cases in hemodialysis centers. Porto Alegre, Rio Grande do Sul, Brazil, 2020
Source: Prepared by the authors.

contamination; to such end, it is necessary that the procedures are well established in the health services and that the team undergoes permanent education[12].

Hemodialysis centers must be able to manage the COVID-19 pandemic, as there is a possibility of an increase in the demand for care; therefore, elaborating a contingency plan to prevent different scenarios is indispensable. It should be noted that, in addition to having a greater number of isolation rooms for treating COVID-19 cases, it is also necessary to consider the other existing cases of isolation

1. Pre-hemodialysis screening

- Ask all patients, at the welcoming moment, about infection symptoms or contact with people presenting such symptoms;
- Maintain suspected cases in a separate physical space until the dialectic appointment, check vital signs and oximetry, ask for evaluation on the part of the nurse and physician;
- Prioritize care for suspected cases;
- In suspected cases, ensure that the patient wears a surgical mask at all times;
- Avoid crowding among the patients from their accommodation at the welcoming to their dialysis point;
- The Nursing team must perform the screening using the recommended PPE: disposable apron, procedure gloves, mask and face shield;
- The patient must sanitize their hands before entering the dialysis room.

2. Referral of suspected cases

- Stable patient: Continue therapy at their dialysis center according to the contingency plan and maintain home isolation until diagnosis is completed;
- Unstable patient: Evaluate dialysis urgency, refer to emergency care, follow recommendations from health agencies.

3. Transit of patients in the health service

- Establish the locomotion flow of the suspected or confirmed case to the hemodialysis room;
- In cases of hospital admission: Transportation to the hemodialysis unit must be done through a specific route and time pre-established by the institution;
- In outpatient cases: Schedule a specific time to come to the dialysis center and, if possible, establish an exclusive entrance.

4. Allocation in hemodialysis rooms

- Perform hemodialysis in a single, well-ventilated room;
- Perform dialysis in the last shift of the day, if possible;
- Maintain isolation by cohort in case of more than one patient;
- Keep suspected and confirmed cohorts in different rooms;
- Use an isolation room for hepatitis B if necessary, preferably with already immune patients and with reactive Anti-Hbs.

5. Infection control measures in the environment

- Have devices for respiratory and hand hygiene and warning signaling/guidelines at the reception and hemodialysis rooms;
- Maintain a minimum distance of 1 meter between chairs in the waiting room;
- Perform care in isolation room with the doors closed and the windows open to favor ventilation;
- Keep patient with surgical mask and professionals with PPE recommended;
- Restrict access to the isolation room to the patient's assistance team;
- Keep in the isolation room only furniture and utensils necessary for assistance;
- Institute precaution and contact/droplet measures during care, and for aerosols when necessary;
- Use standardized solution in the disinfection of materials that allows inactivation of the viral load (quaternary ammonium, chlorine or alcohol based products are recommended);
- Disinfect surfaces before and after use;
- Disinfect equipment used directly with the patient (thermometers, stethoscopes and blood pressure monitors) after each use;
- Perform external and internal disinfection of hemodialysis equipment after use;
- Perform single use of lines and dialyzers;
- Prohibit use of cell phones during patient care;
- Dispose of all the waste generated as potentially infectious (biological waste/white bag);
- Flag and forward materials that are reprocessed (clothing and procedural material) as coming from COVID-19 care.
- Perform terminal cleaning in the room after use.

6. Guidance regarding personal protection equipment

- Wear a waterproof apron: Professionals who remain with the patient during the entire therapy and those who perform eventual procedures with risk of contact with splashes or contact with the patient's body fluids;
- Wear a disposable TNT apron: Professionals who remain with the patient during the entire therapy (in this case, wear it over the impermeable apron and replace it at each close contact or procedure with the patient). Professionals in a specific appointment and without risk of splashing or contact with secretion and bodily fluids of the patient.

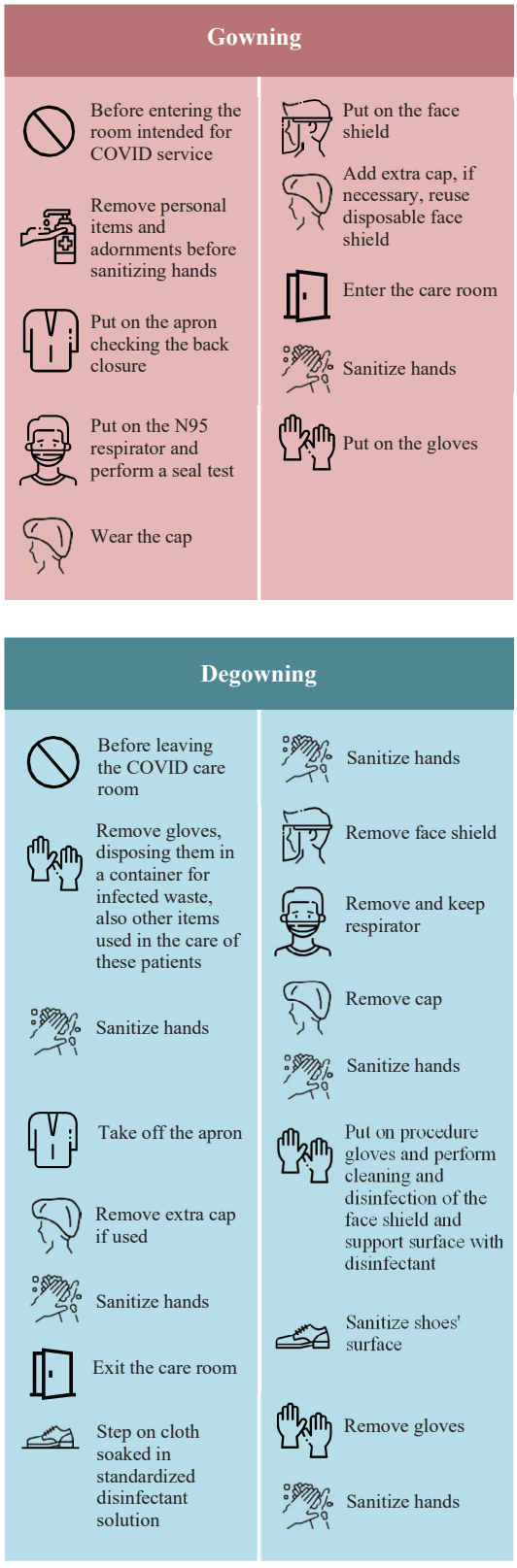

Figure 2 – Flow of care for patients with suspected or confirmed infection by COVID-19 on hemodialysis. Porto Alegre, Rio Grande do Sul, Brazil, 2020

Source: Prepared by the authors.

Team Staffing

- Organize a team sizing that allows for safe and effective care;
- Establish a contingency plan for the care of suspected or confirmed cases with more than one possible scenario (demand);
- Establish reports about the patients' and the team's situation.

- Record of professionals in contact with the patient with a suspected or confirmed diagnosis;
- Monitor the workers' health status. In the front-line professionals, it is recommended to include monitoring of body temperature and of respiratory symptoms;
- Assess the number of professionals distanced due to suspected or confirmed infection by COVID-19;
- Death rate due to COVID-19 among patients undergoing hemodialysis;

Guiding Plan

- Establish a guiding plan for the patients, family members and/or caregivers:

- Encourage social distancing and respiratory/hand hygiene. Establish the weak points and clarify;
- Instruct on environmental control practices: avoid crowding, environmental hygiene, non-sharing of objects and use of masks at the home in case of flu-like symptoms;
- Avoid using public or shared transportation. In case of impossibility, try with respiratory and hand hygiene;
- Reduce exposure time to the hospital environment: arrive close to the appointment time;
- Inform the dialysis center in case of contamination signs and symptoms before commuting to dialysis.

Figure 3 – Managerial plan for hemodialysis centers in the care of COVID-19 cases. Porto Alegre, Rio Grande do Sul, Brazil, 2020
Source: Prepared by the authors.

in hemodialysis, such as patients with multidrug-resistant germs and hepatitis B and C who need to be assisted. This fact is of paramount importance because the Brazilian legislation allows using these rooms at another time for cases other than isolation[18].

Adherence by patients and family members is vital in controlling spread of the disease, especially in patients undergoing outpatient hemodialysis. The multi-professional team must prepare a guiding plan covering all possible contamination sources to which the hemodialysis patient is exposed, as well as identify and act on the weaknesses that prevent adherence by these users[19]. In the field of this study, several training sessions were needed in order to enable the professionals to care for patients with suspected and/or confirmed COVID-19 diagnoses, aiming at safety and quality of care.

In addition to the care taken in elaborating a protocol, its validation is important, as evaluation by an external audience can improve its content and make the instrument more effective. A recent review on the subject matter showed the scarcity of validated protocols and disagreements on the best way to conduct a validation process, especially in relation to the number of evaluators and the form of consensus. Validation by individuals with knowledge of the theme in question is indicated, as well as the inclusion of participants from the target audience[20]. In this study, content validation only includes professionals with expertise in the field. Participation of the patients and family members was not

possible due to the particular characteristic of the situation studied, which involved an unknown and unstable scenario.

FINAL CONSIDERATIONS

Through a literature review and the contribution of specialist professionals, this study allowed elaborating and validating a protocol for the care of patients with COVID-19 in hemodialysis centers. The flows devised allow guiding safe and qualified care by enabling effective decision-making in health urgency situations. This protocol standardized hemodialysis care in order to prevent local contamination outbreaks, and can be used as a care tool, as its implementation is feasible in different health service scenarios.

The study limitations are due to the unprecedented nature of the health situation experienced, as the scientific production in this area has not yet been able to cover all the necessary sectors, with limited published material on the subject matter. This gap in production attests to the importance of this study, which contributes to standardizing the care provided to patients and family members, as well as the professionals' performance. Another limitation is due to the fact that no scale was applied to score the agreement among the experts. However, strategies that enabled 100% consensus were used.

As a contribution to Nursing, it is noteworthy that the protocol can collaborate to maintaining hemodialysis care with protection of patients/family members and health professionals. The protocol was developed based on evidence found to date; however, due to the emergency nature of the disease, more knowledge may emerge and lead to improvements in the recommendations for the clinical practice. Due to the dynamic nature of the information, education of the patient and of the care team to standardize the guidelines was essential and needs to keep happening systematically, as well as the promotion of listening spaces for other questions that may arise.

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