

UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
FACULDADE DE MEDICINA
PROGRAMA DE PÓS-GRADUAÇÃO EM MEDICINA: CIÊNCIAS MÉDICAS

ATENÇÃO A UM PROTOCOLO DE DESMAME DA VENTILAÇÃO MECÂNICA:
07 ANOS DE UM DESAFIO EDUCACIONAL

LUÍS GUILHERME ALEGRETTI BORGES

PORTO ALEGRE

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À meus pais, que me ensinaram valores que transcendem os acadêmicos, aos meus irmãos que sempre me acolheram e a minha esposa Sheila e minha filha Gabriela que me apoiam em todos os momentos.

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“A tarefa não é tanto ver aquilo que ninguém viu, mas pensar o que ninguém ainda pensou sobre aquilo que todo mundo vê.” (Arthur Schopenhauer)

RESUMO

Introdução: A implementação de um protocolo de desmame promove a retirada mais rápida da ventilação mecânica, redução das complicações, redução de falha de extubação e diminuição de custos na unidade de terapia intensiva. Porém, sabe-se que uma nova conduta, comprovada pela literatura, pode levar anos a se tornar um padrão de cuidado na prática diária. **Objetivos:** Investigar a efetividade de um protocolo em relação ao sucesso do desmame e aderência dos médicos assistentes ao protocolo. **Métodos:** Estudo prospectivo de coorte. Nós investigamos todos pacientes consecutivos dependentes de ventilação mecânica por mais de 24 hs no período de janeiro de 2004 à dezembro de 2010 admitidos em uma unidade de terapia intensiva médico cirúrgica. Os dados como idade, sexo, causa da insuficiência ventilatória, escore de apache II, resultado do desmame da ventilação mecânica e aderência médica ao protocolo de desmame foram coletados em todos os pacientes. **Resultados:** Foram incluídos 2.469 pacientes durante 07 anos, sendo 1943 (78%) com sucesso no desmame. A adesão médica ao protocolo de desmame variou durante esses anos, sendo a maior entre 2005 à 2007(38% em 2005 para 86% para 2007 $p < 0,01$). Quando avaliamos o passo à passo do protocolo de desmame, encontramos uma alta adesão para a ventilação não invasiva (VNI)(95%) e para avaliação dos índices preditores de desmame (91%) e uma baixa adesão para controle do balanço hídrico (54%) e interrupção diária da sedação (24%). O sucesso no desmame foi superior nos pacientes que fizeram protocolo de desmame comparado com aqueles que utilizaram a prática clínica como desmame (85,6% x 67,7%, $p < 0,001$). **Conclusão:** A adesão médica ao protocolo de desmame mudou durante os anos do estudo, bem como a implementação das diferentes etapas do protocolo. Isso pode ter ocorrido por diferentes níveis de conhecimento médico e educação oferecidas a equipe do Centro de Terapia Intensiva (CTI) sobre o protocolo de desmame durante os anos do estudo.

Palavras-chave: Ventilação mecânica. Desmame. Protocolo. Terapia intensiva.

ABSTRACT

Background: The implementation of a weaning protocol is referred to an earlier removal from mechanical ventilation (MV), reduction of complication, extubation failure and intensive care unit (ICU) costs. Moreover, it is known that a new approach, proven by literature, may take several years to become standard of care in daily practice. **Objective:** To investigate the effectiveness of a protocol in relation to the success of weaning and adherence of medical assistants to the protocol. **Methods:** We investigated all consecutive patients MV-dependent for more than 24h admitted from Jan-2004 to Dec-2010 in a medical-surgical ICU. Data of age, gender, cause of ventilatory failure, APACHE II score, weaning outcome, and physician adherence weaning protocol were collected in all patients. **Results:** We enrolled 2,469 patients over 7 years, with 1,943 patients (78.7%) of weaning success. The patient's physician-adherence ranged to the weaning protocol changed during the study, being greater adherence from 2005 to 2007 (38% in 2005 up to 86% in 2007, $p < 0.01$). When evaluated weaning protocol step-by-step, we found high adherence for noninvasive ventilation use (NIV) (95%), and for weaning predictor measurement (91%); and lower adherence for control of fluid balance (57%), and for daily interruption of sedation (24%). The weaning success was superior patients that undergone weaning protocol compared to patients that undergone weaning based in clinical practice (85.6% vs. 67.7%, $p < 0.001$). **Conclusion:** The adherence of physicians to a weaning protocol changed during the study years, as well as implementing the different steps of the protocol. This may have occurred by different levels of knowledge of medical and education offered by the ICU staff about the weaning protocol during the period of the study.

Keywords: Mechanical ventilation. Weaning. Protocol. Intensive care unit.

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LISTA DE ABREVIATURAS E SIGLAS

AECOPD = Exacerbação da doença pulmonar obstrutiva crônica

ALI = Doença Pulmonar aguda

APACHE II = Escore de Avaliação Fisiológica Aguda e Crônica de Saúde

ARDS = Síndrome Doença Respiratória Aguda

CHF = Falência Cardíaca Congestiva

CTI = Centro de Terapia Intensiva

DIS = Interrupção Diária da Sedação

IRS (f/Vt) = Índice de Respiração Rápida Superficial

MEP = Pressão Expiratória Máxima

MIP = Pressão Inspiratória Máxima

VM = Ventilação Mecânica

VNI = Ventilação Mecânica Não Invasiva

PFB = Balanço de Fluido Positivo

SOFA = Avaliação da Incidência de Disfunção Orgânica

VEET (SBT) = Ventilação Espontânea com Tubo T (spontaneous breathing trial)

WF = Falha no Desmame

WS = Sucesso no Desmame

WEP = Avaliação dos Preditores de Desmame

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1 INTRODUÇÃO

A Ventilação mecânica é uma modalidade de suporte à vida para pacientes com falência respiratória. O atraso no processo do desmame da ventilação mecânica aumenta a morbidade (por exemplo: pneumonia e trauma das vias aéreas), bem como os custos de uma Unidade de Terapia Intensiva.¹ O uso de um protocolo de desmame da ventilação mecânica pode resultar numa diminuição da duração do tempo total de ventilação mecânica, na duração do desmame e na permanência em dias na Unidade de Terapia Intensiva.² A agressividade em remover o respirador, no entanto, deve ser balanceada, contra a possibilidade de uma interrupção prematura do respirador, pois pode vir acompanhada de uma lista de problemas, entre eles dificuldade em restabelecer as vias aéreas e comprometimento nas trocas gasosas.³ Estima-se que o processo de retirada do suporte ventilatório seja em torno de 42% do tempo total de ventilação mecânica e esse valor pode ser maior ainda caso a resolução pulmonar seja lentamente.³ A taxa de reintubação é desconhecida e varia entre 5 e 15%.¹

O processo de retirada do suporte ventilatório se inicia com o reconhecimento de que o paciente começou a se recuperar dos problemas que necessitaram de suporte ventilatório. Os critérios pelos quais os médicos decidem se o paciente se recuperou o suficiente para tolerar a retirada da ventilação mecânica não foram claramente definidos nem avaliados prospectivamente em ensaios clínicos randomizados. Em vez disso, muitas combinações de critérios subjetivos e objetivos de avaliação, que podem ser marcadores indiretos de recuperação, foram ainda utilizados sem confiança adequada.⁴⁻⁵ Muitos destes preditores fisiológicos já forneceram grandes avanços sobre os mecanismos de falha no desmame.⁶ No entanto, do ponto de vista clínico, os resultados são decepcionantes.¹ Os minutos iniciais do VEET-SBT (Teste de Respiração espontânea com tubo t) deve ser cuidadosamente monitorizado. Os pacientes que toleram devem continuar o VEET-SBT por 30 minutos e não mais do que 120 minutos para garantir a máxima sensibilidade e segurança.⁷ Para os pacientes que passam pelo VEET, a decisão de

extubação deve ser guiada pela avaliação clínica e por dados objetivos para evitar os riscos de reintubações desnecessárias.^{8, 9} Em resumo, os protocolos não devem representar regras rígidas mas, em vez disso, servir de orientações aos cuidados dos pacientes.² A revisão baseada em evidência sugere que o manejo dos protocolos de desmame poderiam reduzir o tempo gasto com pacientes em ventilação mecânica.¹⁰ Mesmo quando as pesquisas mostram uma clara mudança em uma abordagem, não é muito fácil conseguir que os médicos alterem sua prática e estilo.

2 REVISÃO DA LITERATURA

A ventilação mecânica (VM) consiste em um método de suporte ventilatório para o tratamento de pacientes com insuficiência respiratória aguda ou crônica agudizada¹¹. A VM propicia melhora das trocas gasosas e diminuição do trabalho respiratório, podendo ser utilizada de forma não invasiva por meio de uma interface externa, geralmente uma máscara facial e de forma invasiva por meio de um tubo endotraqueal ou cânula de traqueostomia¹². Assim, a VM é aplicada em várias situações clínicas em que o paciente desenvolve insuficiência respiratória, sendo dessa forma incapaz de manter valores adequados de oxigênio e gás carbônico sanguíneos.

Após o paciente se beneficiar com a ventilação mecânica e melhorar a causa da insuficiência respiratória, começa-se a pensar no processo de retirada da vm, ou seja, o desmame da vm que consiste no processo de transição da ventilação artificial para a ventilação espontânea nos pacientes que permanecem em ventilação mecânica invasiva por tempo superior à 24h. Retirar o paciente da vm pode ser mais difícil que mantê-lo. Alguns autores descrevem o desmame como a “área de penumbra da terapia intensiva” e que pode ser considerada uma mistura de arte e ciência¹³. Apesar disso, a literatura tem demonstrado mais recentemente que protocolos de identificação sistemática de pacientes em condições de interrupção da ventilação mecânica podem reduzir significativamente sua duração. Define-se sucesso do desmame da vm a manutenção da ventilação espontânea durante pelo menos 48h após a interrupção da ventilação artificial. Considera-se fracasso ou falência do desmame, se o retorno à ventilação artificial for necessário nesse período. É primordial a identificação precisa dos pacientes hábeis para iniciar o processo de desmame da vm para um desfecho de sucesso. Os profissionais de saúde envolvidos diretamente com a assistência dos pacientes críticos tendem a subestimar a capacidade para reassumir a respiração espontânea quando baseados somente na experiência clínica. O julgamento subjetivo possui baixa sensibilidade (capacidade de prever o sucesso) e especificidade (capacidade de prever a falha).²⁻⁹

Para saber se um paciente tem condições de ser extubado, hoje na literatura define-se como “teste de prontidão” que consiste de critérios clínicos objetivos derivados de estudos observacionais e tidos como preditores de um desmame seguro.¹⁴ Divide-se em critérios exigidos e opcionais, sendo os exigidos: causa da insuficiência respiratória resolvida; $PaO_2/FiO_2 \geq 150$ mmHg ou $SpO_2 \geq 90\%$ com $FiO_2 \leq 40\%$ e $PEEP \leq 5$ cm H₂O; $pH > 7,25$; Estabilidade hemodinâmica (sem drogas vasopressoras ou em doses baixas) e capacidade de iniciar um esforço de inspiração. E como critérios opcionais: Hemoglobina ≥ 8 a 10 mg/Dl; temperatura ≤ 38 graus C e Estado mental acordado e alerta ou que facilmente desperta. É recomendado que o desmame seja iniciado com base nos critérios citados acima, ao invés de qualquer teste fisiológico, como Pressão Máxima Inspiratória ($PI_{max} < -30$ cmH₂O), pressão de oclusão ($P_{0,1} < 4-6$ cmH₂O), índice de respiração rápida e superficial (IRRS < 105 irpm/L). Embora seja reconhecida a superioridade do IRRS em relação aos demais, sabe-se que seu resultado é mais confiável quando indica falha do desmame (IRRS > 105 irpm/L).¹⁴ Atualmente na literatura sabe-se que o melhor método de desmame é a realização do desmame com redução da PSV até 7 cmH₂O ou teste tubo t, sendo este devendo ser realizado entre 30 e 120 min.¹⁵

Protocolos de desmame:

Em 1973, Sahm, já demonstrava que o protocolo de desmame da vm se baseava na questão do médico, porém já havia uma identificação do paciente que está apto para ser desmamado da vm, já se decidiam sobre qual o método de desmame e ainda as decisões eram bastante influenciadas pelo julgamento e experiência do médico.¹⁶ Em alguns casos, os médicos tendem a subestimar a probabilidade de interrupção de sucesso do desmame da vm.¹⁷ Stroetz, 1995 mostrou que previsões com base no julgamento sozinho, tem baixa sensibilidade (capacidade de prever o sucesso) e especificidade (capacidade de prever a falha).¹⁸ Ely, em 1996, mostrou que uma triagem diária dos pacientes em ventilação mecânica seguido de um teste de respiração espontânea pode reduzir o tempo de vm.¹⁹ Em 1997, Kollef demonstrou que protocolos dirigidos por terapeutas respiratórios e enfermeiros apresentaram um tempo de desmame menor que o realizado por médicos.²⁰ Em 2001, no consenso de desmame da ventilação

mecânica sugere-se que o protocolo de desmame da vm seja dirigido por profissionais não médicos e sim por enfermeiros e / ou terapeutas respiratórios e fisioterapeutas. Chatburn em 2007, comprovou que não existe um protocolo específico, mas que a aplicação de algum protocolo consegue acelerar o processo da descontinuação da ventilação mecânica e reduz tempo de desmame e tempo de vm.²¹

Bolles em 2007, definiu que o desmame deve ser dividido em 3 fases: desmame fácil, desmame difícil e desmame prolongado e que devemos iniciar o processo de desmame o mais rápido possível. Define-se como desmame fácil quando o paciente é extubado sem que apresente nenhuma falha no primeiro teste de respiração espontânea e que permaneça em ventilação espontânea por 48 hs após a extubação. Já desmame difícil é quando há a necessidade de se realizar até três testes de respirações espontâneas ou até 07 dias de tempo de ventilação mecânica e desmame prolongado é quando o paciente falha em mais de 03 testes de respirações espontâneas ou permanecem em vm por mais de 07 dias após o primeiro teste de respiração espontânea. Em 2008, Girard concluiu que existe métodos eficazes de protocolos para desmame, mas este conhecimento muitas vezes não é aplicado por médicos na prática clínica.

Um protocolo de desmame é um guia estruturado para reduzir, ou descontinuar, ou ambos, o suporte ventilatório mecânico, e que, geralmente contém três componentes. O primeiro componente é uma lista de critérios objetivos baseados em fatores clínicos gerais usados para ajudar a decidir se um paciente está pronto para respirar sem a ajuda de um ventilador, muitas vezes referida como "prontidão para desmamar" critérios (como o utilizado pelo Ely 1996). O segundo componente consiste de orientações estruturadas para reduzir o suporte ventilatório. Isto pode ser abrupta (por exemplo, ensaios de respiração espontânea) ou gradual, utilizando uma redução gradual no suporte para atingir a interrupção (por exemplo SIMV ou PSV), tal como o usado por Brochard 1994, 1995 Esteban, Kollef 1997 e 2000. O terceiro componente é constituído por uma lista de critérios para decidir se o doente está pronto para ser extubado (tais como os utilizados por Hendrix 2006). Em muitas UTIs, os protocolos são apresentados como guias escritos ou algoritmos e definições do ventilador são ajustados manualmente pelos profissionais de saúde²².

Assim, o protocolo é um auxílio na prática médica, é uma ferramenta de apoio a decisão, é um plano detalhado de uma experiência científica ou médica.¹

O protocolo reduz variações desnecessárias ou prejudiciais nessa abordagem, prevê regras específicas para tomada de decisões e é seguro e objetivo para retirada da vm.⁸ Além disso se baseia no princípio de que o conhecimento de um grupo coletivo é geralmente melhor do que a de um indivíduo, melhora a prática e reduz a influência da subjetividade do julgamento e experiência.²²

Os médicos têm diferentes experiências, habilidades e filosofias de desmame, assim existe um grande potencial de variação. Como resultado, tem havido um crescente interesse em estabelecer uma prática mais consistente em UTIs através do desenvolvimento e utilização de protocolos de desmame que fornecem orientação estruturada. Os protocolos baseiam-se no princípio de que o conhecimento de um grupo coletivo é geralmente melhor do que a de um indivíduo. Protocolos destinam-se a reduzir a variação, para melhorar a eficiência da prática, reduzindo a influência da subjetividade do julgamento e experiência, e procurando aplicar objetividade²². Além disso, eles podem capacitar o enfermeiro e fisioterapeuta para iniciar o processo de desmame precoce da ventilação mecânica, identificando os pacientes que estão prontos para serem desmamados da vm. Uma revisão sistemática²² concluiu que os protocolos de desmame são seguros e eficazes na redução do tempo gasto em ventilação mecânica. Também foram encontrados dados consideráveis no resultado de duração total e desmame da ventilação. Há evidências de redução da duração da ventilação mecânica, duração do desmame e tempo de internação em UTI com uso de protocolos de desmame padronizados. As reduções são mais prováveis de ocorrer em UTIs médico, cirúrgico e geral, mas não em UTI neurocirúrgica. No entanto, a heterogeneidade significativa entre os estudos indica cautela na generalização dos resultados. Alguns autores do estudo sugerem que o contexto organizacional pode influenciar os resultados; no entanto, estes fatores não foram considerados em todos os estudos incluídos e não poderia ser avaliada. Futuros ensaios clínicos devem considerar a avaliação do processo de entrega de intervenção para distinguir entre os efeitos de intervenção e implementação. Ensaios randomizados de protocolos de desmame estão continuando e a adesão aos protocolos está crescendo mundialmente. Pesquisas

mostram relatos de uso em UTIs de 8% na Grécia, 56% na Itália, Dinamarca e Noruega, 61% no Reino Unido, 68% na Suíça e Países Baixos (Rose 2011), 22% na Polónia (Kubler 2013), e 71 % no Canadá (Ellis 2012). Por estas razões é importante que os achados de estudos recentes são sintetizados para orientar a prática futura.

3 JUSTIFICATIVA

Protocolos de Desmame da ventilação mecânica parecem ser uma boa estratégia para o gerenciamento do processo de retirada do suporte ventilatório. A aplicação dos protocolos tem resultados melhores que simplesmente o julgamento clínico. No entanto, sabemos que a inserção de uma nova rotina que envolva uma equipe assistencial não parece ser simples; assim, gostaríamos de fazer a mensuração desse processo de implantação e acompanhamento dos resultados no que diz respeito à adesão médica ao protocolo e ao seu desfecho de sucesso ou fracasso na sua aplicação.

4 OBJETIVOS

Avaliar a efetividade de um protocolo em relação ao sucesso no desmame da ventilação mecânica.

Avaliar a adesão médica às diferentes etapas do protocolo de desmame da ventilação mecânica.

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7 ARTIGO EM INGLÊS

Attention to Weaning from Mechanical Ventilation Protocol: 7 years of Educational Challenge

ABSTRACT: Background: the implementation of a weaning protocol is referred to an earlier removal from mechanical ventilation (MV), reduction of complication, extubation failure and intensive care unit (ICU) costs. Moreover, it is known that a new approach, proven by literature, may take several years to become standard of care in daily practice. **Objective:** To investigate the effectiveness of a protocol in relation to the success of weaning and adherence of medical assistants to the protocol. **Design:** Prospective cohort study. **Patients and methods:** We investigated all consecutive patients MV-dependent for more than 24h admitted from Jan-2004 to Dec-2010 in a medical-surgical ICU. Data of age, gender, cause of ventilatory failure, APACHE II score, weaning outcome, and physician adherence weaning protocol were collected in all patients. **Results:** We enrolled 2,469 patients over 7 years, with 1,943 patients (78.7%) of weaning success. The patient's physician-adherence ranged to the weaning protocol changed during the study, being greater adherence from 2005 to 2007 (38% in 2005 up to 86% in 2007, $p < 0.01$). When evaluated weaning protocol step-by-step, we found high adherence for noninvasive ventilation use (NIV) (95%), and for weaning predictor measurement (91%); and lower adherence for control of fluid balance (57%), and for daily interruption of sedation (24%). The weaning success was superior patients that undergone weaning protocol compared to patients that undergone weaning based in clinical practice (85.6% vs. 67.7%, $p < 0.001$). **Conclusion:** The adherence of physicians to a weaning protocol changed during the study years, as well as implementing the different steps of the protocol. This may have occurred by different levels of knowledge of medical specialties and education offered by the ICU staff about the weaning protocol during the period of the study.

Keywords: Mechanical ventilation. Weaning protocol. Intensive Care Unit.

INTRODUCTION

Mechanical ventilation (MV) support is a critical life sustaining modality for patients with respiratory failure. Delay in the weaning process increases the morbidity (e.g., pneumonia and airway trauma) as well as the Intensive Care Unit (ICU) costs.¹ Use of a weaning protocol can result in decreased total duration of mechanical ventilation, weaning duration, and length of stay in intensive care unit.¹¹ Aggressiveness in removing the ventilator, however, must be balanced against the possibility that premature discontinuation may occur, with a set of problems, including difficulty in reestablishing artificial airways and compromised gas exchange.² Esteban et al estimated that as much as 42% of the time a medical patient spends on a MV is during the withdrawal process, and that percentage is likely to be much higher with a patient who has a more slowly resolving lung process.² The optimal rate of reintubation is unknown, it would seem likely to rest between 5% and 15%.¹

The process of discontinuing MV support begins with the recognition that the patient has begun to recover from the problems that necessitated ventilatory support. The criteria by which clinicians decide whether the patient has recovered enough to tolerate withdrawal of ventilatory support have not been clearly defined nor prospectively evaluated in randomized controlled trials. Instead, many combinations of subjective and objective assessment criteria that may be surrogate markers of recovery have been employed still with no adequate confidence 3-7. Many of these physiologic predictors already have provided great insights into the mechanisms of the failure of liberation 38. However, from a clinical point of view, the results are disappointing 1.

The initial few minutes of the spontaneous breathing trial (SBT) should be closely monitored. The tolerant patients should continue the SBT for at least 30 min but no more than 120 min to assure maximum sensitivity and safety 8. For patients who pass the SBT, the decision to extubated must be guided by clinical judgment and objective data to minimize the risk of unnecessary reintubations 9, 10. In summary, protocols should not represent rigid rules but, rather, guides to patient care 11.

The evidence-based review suggests that protocols to manage the weaning and liberation of patients from MV could reduce the time that patients spend receiving MV 12. Even when research clearly supports a change in approach, it is

very difficult to get physicians to alter their practice and management styles. The purpose of this study was to evaluate the success of weaning protocol and medical adherence to its implementation.

PATIENTS AND METHODS

Design

This was a prospective cohort clinical study, and was approved by the Ethic Research Committees of the Institution.

Patients

The study was conducted over 7-years in a 31-bed medical-surgical ICU. The study enrolled all critically ill who received MV for 24h or more, with Servo 900C® (Siemens-Elima, AB, Sweden) or Evita 2-Dura®, and Evita 4® (Dräger Medical AG – Germany).

Study weaning protocol

The implementation of the protocol began in January 2004 and was divided into three phases:

Phase 1: Implementation (2004), Phase 2: Application of the Protocol (2005,2006,2007) and Phase 3: Monitoring Protocol (2008,2009,2010). The data were presented and actualized to ICU-staff each two years in programmed meetings. The institutional protocol was developed with multidisciplinary planning (physician, physiotherapist and nurse) and required no additional support personnel for its implementation. The five steps of the institutional weaning protocol were:

(1) Avoids positive fluid balance 24h previous to weaning trial. Fluid balance is a potentially modifiable variable associated with weaning outcomes.

(2) Daily interruption of sedation defined by ICU-staff or patient's assistant-physician. Patients with improvement or resolution of the underlying cause of acute respiratory failure; adequate gas exchange as indicated by a PaO₂ above 60mm Hg while breathing with an FIO₂ of 0.4 or less with a positive end-expiratory pressure (PEEP) of 8cm H₂O or less; low or no further need for vasoactive agents (dopamine or dobutamine $\leq 5 \mu\text{g}/\text{kg}$ per min, or norepinephrine $\leq 0.05 \mu\text{g}/\text{kg}$ per min), and no evidence of increased intracranial pressure, undergone daily screen interruption of sedation.

(3) Weaning predictor evaluation. These measurements of ventilatory parameters had been recorded at 1-3 minutes of SBT: frequency to tidal volume ratio (f/VT) measured with a spirometer (Ainca model 295, Electronic Respirometer, USA), during one minute of monitoring with the patient in semi recumbent position; the maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP) were measured with an aneroid manometer (Suporte, Famabra – Brazil) and defined as the most negative (and positive, respectively) value produced by three consecutive respiratory efforts after 30 seconds of occlusion against a unidirectional valve (NIF-TEE – non re-breathing T-Piece, Smiths Medical – Keene, NH). To measure MIP the inspiratory port of the valve was blocked permitting only exhalation, thus allowing patients to perform the maximal inspiratory effort at a lung volume approaching residual volume. To measure MEP the expiratory port of the valve was blocked permitting only inhalation, thus allowing patients to perform the maximal expiratory effort at a lung volume approaching the total lung capacity 14.

(4) T-tube trial during 30 to 120 minutes. Patients with f/VT lower than 105 breaths/L/min and MIP lower than - 30cm H₂O had been submitted to 30 min of SBT with T-tube trial enriched by oxygen to achieve arterial oxyhemoglobine saturation (SpO₂) >90% measured by pulse oximetry. Extubation had been made after adequate clinical tolerance to SBT, defined as respiratory rate (RR) <38 breaths/min, SpO₂ >90%, heart rate <130 beats/min, with no hemodynamic instability (changes <20% for systolic or diastolic arterial pressures), with no change in mental status (drowsiness, coma, anxiety), without signs of respiratory discomfort, diaphoresis or signs of increase work of breathing (such as the use of accessory respiratory

muscles or paradoxal thoracoabdominal muscular ventilations). Patients without clinical tolerance returned to MV and the weaning trial must be repeated at day after.

(5) Noninvasive ventilation (NIV) use in selected patients. The NIV was indicated if the patients plus one or more of the following characteristics: (a) more than one consecutive failure of weaning trial; (b) patients with chronic heart failure (CHF); (c) patients with chronic obstructive pulmonary disease (COPD); (d) upper airway stridor after extubation not requiring immediate reintubation; and (e) signs of muscle weakness and ineffective cough.

The weaning protocol always had been presented to the patient's attending physician (neurosurgeon, neurologists, cardiologists, pulmonologists, internal medicine physicians or intensivists) and, if he/she agrees, it was applied.

Data collection and monitoring:

All enrolled patients were followed during the ICU-stay. The data evaluated were: (a) weaning success (WS) or failure (WF); (b) ICU-mortality; (c) patient's attendant-physicians full adherence to the protocol. Full adherence was considered when physician adhered to a minimum of 4 steps of the weaning protocol; and (d) patient's attendant-physicians adherence partially to the protocol (evaluation of each steps of the protocol). We also collected data of age, gender, cause of the respiratory failure, Apache (Acute physiology and chronic health evaluation) II score, and SOFA (Sequential Organ Failure Assessment) score.

Statistical analysis:

Results were reported as means \pm standard deviation (\pm SD) or numbers (and percentages in brackets). Patients' characteristics were compared using the chi-square test, for categorical variables, and the t-student test or Mann-Whitney U test for continuous variables. All tests were two-sided, and p-values of <0.05 were considered statistically significant. Analyses were done using the Statistical Package for Social Science (SPSS 20.0 Inc; Chicago IL, USA) software.

RESULTS

Demographic variables

The study enrolled 2,469 patients (Figure 1). Of these, 1,943 patients (78.7%) had WS. The WS was higher in full-protocol patients compared to non-full protocol patients (85.6% vs. 67.7%, $p < 0.001$). The Apache II score was 15 ± 7 and 58% (1,432/2,469) of the patients were male. The total mortality rate was 14.8%, 234 patients in WS group and 133 in WF group (12% vs. 25.2%, $p < 0.01$). The baseline characteristics of the patients were presented in Table 1.

Evaluation of full physician-compliance to the weaning protocol

Compliance with the protocol was monitored as described in Methods section. The patient's physician-adherence full to the weaning protocol occurred in 1,488 of the cases (60.3%), and changed significantly over 7 years of the study (38% in 2005 vs. 86% in 2007, $p < 0.001$), and that physician-adherence increased between 2005 and 2007, it remained in 2008 and decreased in 2009 and 2010 as showed in Figure 2. We observed an increasing of physician compliance during first years (2004 to 2007), coincident with period of staff and attendant-education. After 2009, the compliance to protocol decreased until 50%, coincidently with the finish of the protocol-orientation given to staff and attendant-physician. The full-protocol WS remained more constant during the study years (mean 85.7%, variation 81.6% to 90.9%) when compared to non-full protocol WS (mean 67.7%, variation 55.3% to 79.5%). During the study years WS of all patients increased (73,1% in 2004 to 85,4% in 2010, $p < 0.001$).

Evaluation of physician-compliance to each step of protocol

When evaluated weaning protocol step-by-step, we found high physician-adherence for NIV use (95%), and for weaning predictor evaluation (91%). Lower adherence occurs for fluid balance control (57%), and for daily interruption of

sedation (24%) as showed in figure 3. NIV was used in 67% of the patients (1,654/2,469), which represent, as described previously in step 5, that 95% of the patients who met criteria to use it did it.

DISCUSSION

This study demonstrates the feasibility and challenges of implementing a previously validated protocol for discontinuation of MV.

We know that WF has a significant independent association with increased hospital mortality for general surgical and medical patients⁸. In addition, unsuccessful extubation significantly prolongs the duration of MV; ICU and hospital stay, and increase the need for tracheotomy¹⁵. A protocol is “a detailed plan of a scientific or medical experiment, treatment, or procedure”, and may be considered a decision-support tool when used in clinical practice, a tool that lies somewhere between a completely autonomous clinician and a wholly automated computerized treatment in the spectrum of approaches to medical practice.¹² An “adequately explicit” protocol provides specific rules for decision-making based on patient data. Protocols use aim to safely and efficiently liberate patients from MV, reducing unnecessary or harmful variations in this approach.⁹

Blackwood et al¹⁶ showed that weaning based in institutional protocols did not reduce the MV time, and it was not associated with increases reintubation rate or ICU mortality. In a recent publication, Tanios et al¹⁷ demonstrated that including f/VT in a protocol prolonged weaning time (2 vs. 3 days, $P= 0.04$); in addition, this predictor did not conferred survival benefit or reduced the incidence of WF. In a multicenter randomized controlled trial, with concealed allocation, compared usual care for weaning with computer-driven weaning, and the investigators found reduction of weaning duration (5 to 3 days, $P= 0.01$) and total duration of MV (12 to 7.5 days, $P= 0.003$), however, reintubation rate did not differ (23% vs. 16%, $P= 0.4$)¹⁸. According data of Kollef et al¹⁹, protocol-guided weaning of MV is safe and led to extubation more rapidly than physician-directed weaning. The rate of WS was significantly greater for patients receiving protocol-directed weaning compared with patients receiving physician-directed weaning (RR: 1.31; 95%CI: 1.15-1.50, $P= 0.03$), but the

hospital mortality was similar (22.3% vs. 23.6%, $P = 0.77$). Kiracly et al compared the use of the protocol in COPD, the protocol group obtained effectiveness in successful extubation (98% x 78% $P = 0.014$), shorter in duration of mechanical ventilation (3.1 x 5.0 days $P < 0.001$) days in the ICU (6 x 12 days $P < 0.001$)³⁹.

Mc Leal et al shown that Implementing the Model for Accelerating Improvement improved understanding of and adherence to protocol-directed weaning and reduced the rate of unsuccessful extubations.⁴⁰ After the intervention, the rate of unsuccessful extubations decreased, and staff's understanding of and adherence to the weaning protocol increased significantly. The rate of ventilator-associated pneumonia, duration of mechanical ventilation, and staff's perceptions of the practice safety climate did not change significantly.⁴⁰

In a recently published meta-analysis, Blackwood et al⁴¹ showed that there is evidence of reduced duration of mechanical ventilation, weaning duration and ICU length of stay with use of standardized weaning protocols. Reductions are most likely to occur in medical, surgical and mixed ICUs, but not in neurosurgical ICUs. However, significant heterogeneity among studies indicates caution in generalizing results. Some study authors suggest that organizational context may influence outcomes, however these factors were not considered in all included studies and could not be evaluated. Future trials should consider an evaluation of the process of intervention delivery to distinguish between intervention and implementation effects. There is an important need for further development and research in the neurosurgical population⁴⁰. We included 17 trials (with 2434 patients) in this updated review. The original review included 11 trials. The total geometric mean duration of mechanical ventilation in the protocolized weaning group was on average reduced by 26% compared with the usual care group ($N = 14$ trials, 95% confidence interval (CI) 13% to 37%, $P = 0.0002$). Weaning duration was reduced by 70% ($N = 8$ trials, 95% CI 27% to 88%, $P = 0.009$); and ICU length of stay by 11% ($N = 9$ trials, 95% CI 3% to 19%, $P = 0.01$). There was significant heterogeneity among studies for total duration of mechanical ventilation ($I(2) = 67\%$, $P < 0.0001$) and weaning duration ($I(2) = 97\%$, $P < 0.00001$).

The first step of our approach was to avoid positive fluid balance 24-48h before weaning trial. Some evidence that negative fluid balance can positively influence weaning outcome has been described ^{13, 20, 21}, and the use of diuretic therapy at this time can also cause hypotension. This is an important issue to consider to maximize the successfully of weaning, because this population usually receives large volume resuscitation at arrival at the emergency department or in the ICU, based in “early goal approach”. In our study, the fluid balance is a potentially modifiable variable associated with weaning outcomes. To avoid the positive fluid balance (PFB) the protocol recommend use of diuretics in the previous 24h to extubation ¹³.

The second and fourth steps of the protocol involved the daily interruption of sedation. Namen et al ²² and Randolph et al ²³ found that weaning protocols that do not address level of consciousness may be ineffective in some ICUs. In light of this evidence, any approach to weaning must consider level of consciousness and sedation status in addition to respiratory function and mechanical ventilator settings. The “wake up and breathe” protocol includes an evaluation of sedation status and a SBT, which are paired with a weaning screen ^{24, 25}. In a multicenter randomized trial that enrolled 335 medical ICU subjects, Girard et al ²⁵ found that the two-step protocol (“wake up and breathe”) reduce MV-dependency days (14.7 vs. 11.6 days during the 28-day study period; mean difference, 3.1 days, 95%CI: 0.7-5.6, P <0.02). In our study we found a low adherence to this stage of the protocol, about 24%, although proven in the literature this is an unusual practice by attending physicians, as opposed to when the ICU physicians manage the weaning protocols, for this practice already it is well known to them. A once-daily trial of T-tube trial may be the most effective method of detect the adaptive changes of this instable period, because this approach meets the three principal requirements of conditioning program: overload, specificity and reversibility ^{1, 8}. In our study, when evaluated the tube t test as part of the weaning protocol found that 82% was joining the test tube t, having a good acceptance with the attending physician, most likely because it is a method already well known and accepted in the literature . ⁸

The third step of our protocol was measurements of the classical ventilatory weaning predictors. An f/VT value of 105 breaths per min per liter best differentiated

patients who were successfully weaned (below 105) from those in whom weaning failed (above 105) 1, 26. The positive and negative predictive values were 0.78 and 0.95, respectively, which were the highest values noted for any of the predictive indices in the study 26. Several studies disagree with the systematic use of f/VT , because its accuracy is not reproducible for all ICU subpopulations 4. An $f/VT \leq 105$ has been adopted worldwide as a cutoff point to predict weaning success. MIP, a global assessment of the strength of all the respiratory muscles, is a classic indices used to predict weaning outcome. An early study found that a MIP value of -30 cmH₂O or less predicted successful weaning, while a MIP value higher than -20 cmH₂O predicted weaning failure. However, in subsequent studies, these threshold values have exhibited poor sensitivity and specificity 3, 4, probably because MIP assesses only the strength of the respiratory muscles without taking into account the demands being placed upon them. MIP measurement was associated with high likelihood ratios that translate into large, clinically significant changes in the probability of success or failure, but these are not easy to measure and too few patients have been studied 3. Our results showed that in the daily clinical practice, the evaluation of weaning parameters greatly attracts and is solicited by attending physicians. About 91% of patients had weaning parameters evaluated, confirming the large adoption of this issue in clinical practice.

Furthermore, NIV was widely approved as a tool to improve weaning outcome. In our study, the NIV use was the most accepted step of weaning protocol, used in 95% of patients. NIV has been studied for three different indications. First, NIV has been used as an alternative weaning modality for patients who are intolerant of the initial weaning trial 27, 28. Secondly, NIV has been used as a treatment option for patients who have been extubated but developed ARF within 48 h 29, 30. Thirdly, NIV has been used as a prophylactic measure after extubation for patients who are at high risk for reintubation but who did not develop ARF 31, 32. In our weaning protocol, NIV was implemented as a weaning modality for COPD patients and a prophylactic measure for high risk patients (step 5). These circumstances appear very appealing to attending physicians, moreover the large experience of ICU staff could contribute to the high use of NIV in clinical practice. The use of NIV shows an increasing worldwide both for COPD and hypoxemic respiratory failure 33.

This experience demonstrated that a commitment to the successful implementation of the weaning protocol was necessary on the part of the hospital and its administration in order to insure its success. The initial outlay of resources, including dedicated monitoring staff, and the time of physiotherapist and respiratory nurses to attend in-services, was essential. In addition, we have identified significant practical barriers to protocol implementation such workload of ICU staff and the attending physician acceptance. Although many aspects of these findings are unique to our ICU, several observations have important implications for institutions currently dealing with the need for a more systematic approach to the weaning from MV. Implementation strategies aimed at increasing acceptance of and adherence to this and other evidence-driven protocols are essentials to obtaining optimal outcomes. The factors that affect clinical guideline adoption are complex, as are the social norms, administrative processes, and local systems that must be aligned to execute such protocols 34. The emerging field of implementation science aims to make the uptake of research findings into routine healthcare efficient and predictable. Accordingly, this field is rapidly developing new theory and practice 35, 36. The ICU environment (high-risk, high-cost, and problem prone) would seem to be an early and appropriate target for this new science. Also it has been shown that a newly proven therapy may take up to 20 years to become standard of care 37. 'Knowledge transfer' is a 'new science' but an old practice, and limitations on translating knowledge into clinical practice are well characterized. This phenomenon can be observed in Figure 2, in which we observe an increasing in weaning success rate in the group who carried out the protocol. This may have occurred due to a improved knowledge of weaning acquired over the years, even physicians are not adhering to all steps of protocol. Lots of barriers exist in implementing knowledge into the clinical field, and these may be related to many different causes: e.g. conservatism, lack of the knowledge, and inability to overcome the inertia of previous practices. Also, the implementation of recommendations and guidelines usually requires a high workload, and training needs to be maintained to keep up compliance with these guidelines.

The implementation of ventilator weaning protocol can reduce reintubation rate, and consequently mortality, without decrease the length of time that a patient spends on the ventilator. The protocol should be organized and easy to be implemented by a multidisciplinary team. It is imperative that protocols not be used to

replace clinical judgment, but rather to complement it. More studies regarding the impact of protocol-based weaning are needed to better delineate optimal approaches in specific patient populations and to validate weaning predictors used on weaning protocols.

STUDY LIMITATIONS

Change in treatment team during the years of the study;

Difficult to manage and require the use of a new routine in healthcare staff;

ICU open for medical assistants, difficulty in deploying new approaches

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Table 1: Baseline characteristics of 2,469 ventilated patients*

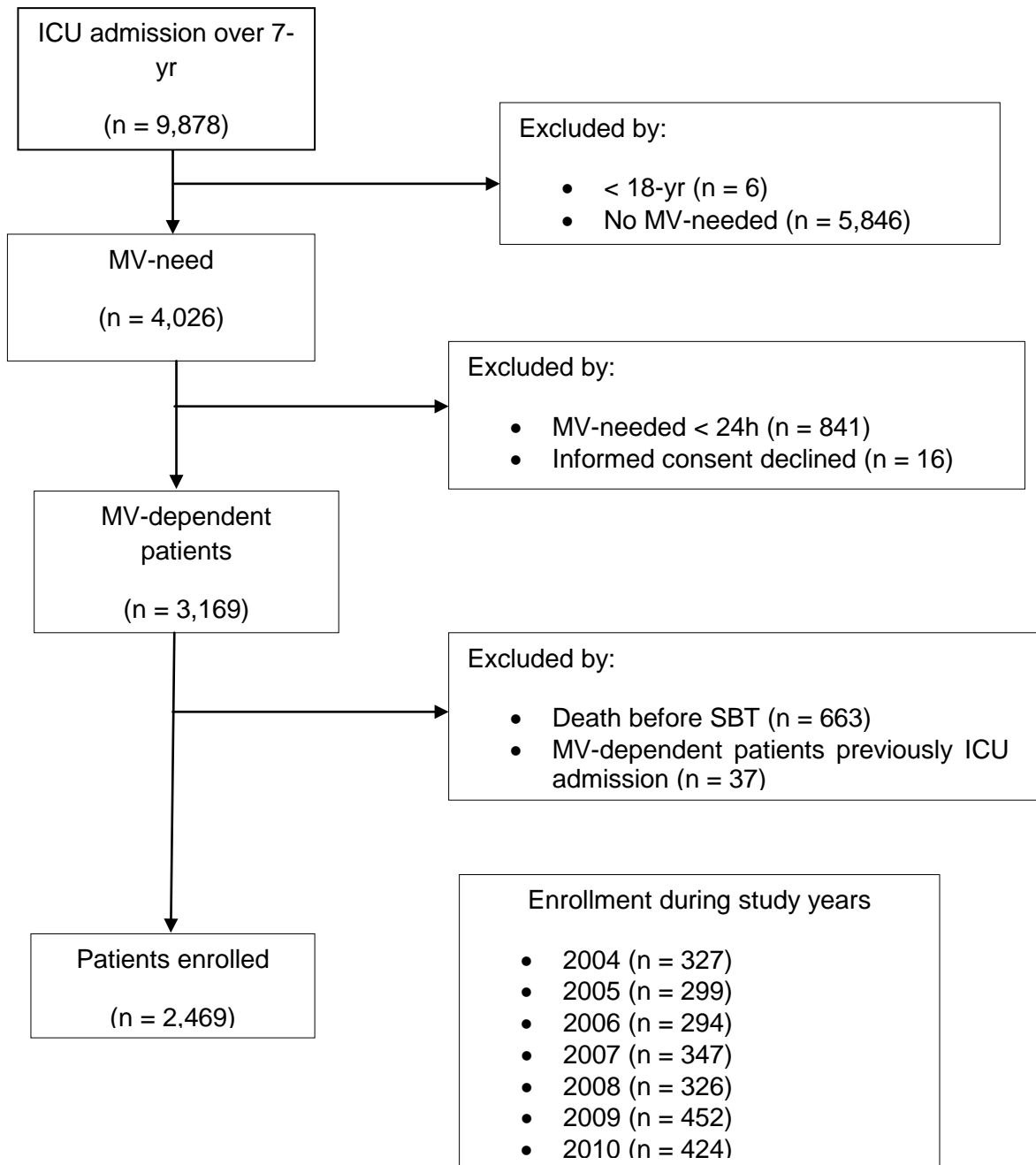
Characteristics	All patients n = 2,469	WS n = 1,943	WF n = 526	<i>p</i> (comparing WS and WF)
Age, yrs	65 ± 16	64 ± 14	66 ± 17	0.005
Male gender (%)	1,432 (58)	1,143 (58.8)	289 (54.9)	
Apache II score	15 ± 7	14 ± 8	15 ± 3	0.005
SOFA score	3.2 ± 1.5	2.6 ± 1.2	3.3 ± 1.8	<0.0001
Glasgow coma score	14 ± 1.1	14 ± 1.2	14 ± 0.7	0.99
Respiratory failure cause (%)				
ALI or ARDS	852 (34.5)	667 (34.4)	185 (35.2)	
Post-surgical	708 (28.7)	567 (29.2)	141 (26.8)	
AECOPD	406 (16.5)	345 (17.8)	61 (11.6)	
Stroke	120 (4.9)	65 (3.3)	55 (10.5)	<0.0001
CHF	345 (13.9)	270 (13.8)	75 (14.2)	0.88
Trauma	38 (1.5)	29 (1.5)	9 (1.7)	0.84
MV days	7 ± 3	5 ± 2	10 ± 5	<0.00001
Mortality (%)	367 (14.8)	234 (12)	133 (25.2)	<0.00001

* Data are expressed as mean ± SD

Definitions of abbreviations: AECOPD = acute exacerbation of chronic obstructive pulmonary disease, ALI = acute lung injury, APACHE II = Acute Physiology and Chronic Health Evaluation score II, ARDS = acute respiratory distress syndrome, CHF = congestive heart failure, SOFA = Sequential Organ Failure Assessment score, WF = weaning failure, WS = weaning success

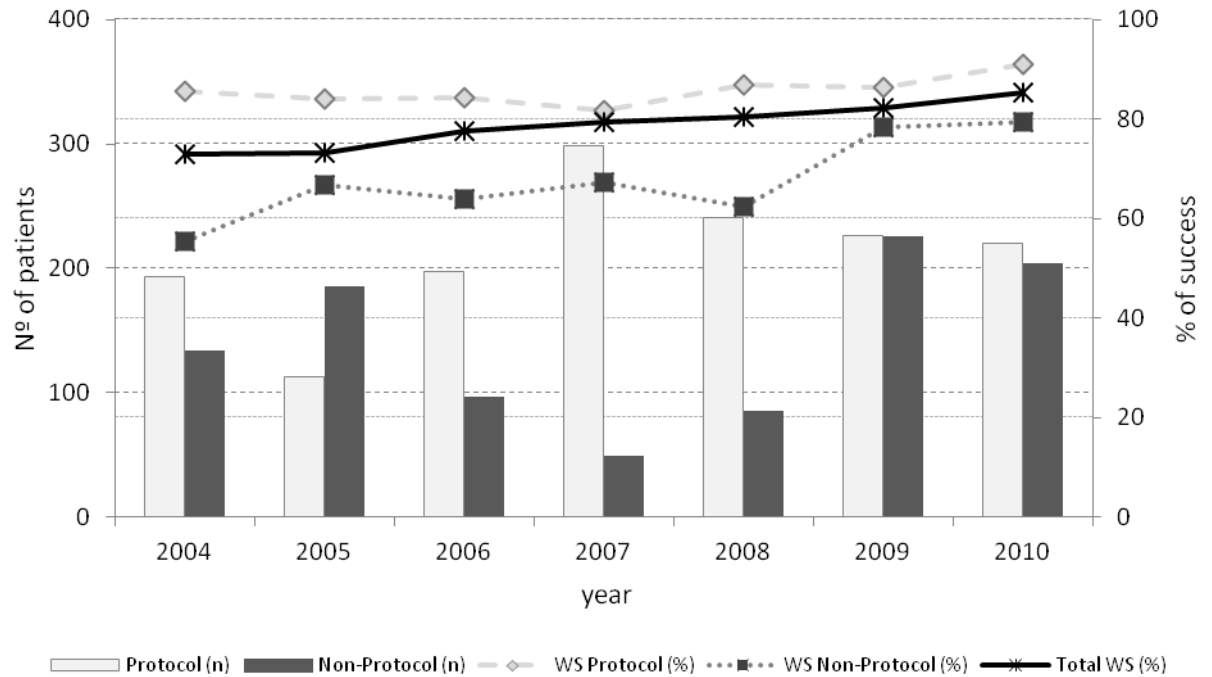
Tabela 2. Comparação da taxa de sucesso dos pacientes protocolos e não protocolos em relação aos períodos de avaliação.

Período de Avaliação	WEANING SUCCESS (%)		p-valor
	Protocol	Non- Protocol	
2004	85,5	55,3	<0,0001
2005	84,1	66,7	0,007
2006	84,3	64,0	0,002
2007	81,6	67,4	0,032
2008	86,8	62,4	<0,0001
2009	86,3	78,4	0,201
2010	90,9	79,5	<0,0001

Figure 1: Trial profile

Definitions of abbreviations: ICU = Intensive care unit; MV = mechanical ventilation; SBT = spontaneous breathing trial

Figure 2: Histogram showing the number of patients had undergone weaning by full protocol (gray) or by physician-decision (non-full protocol) (black) over 7 years. Lines represent percentage of WS in protocol, total patients, and non-protocol patients.



Definitions of abbreviations: WS = weaning success

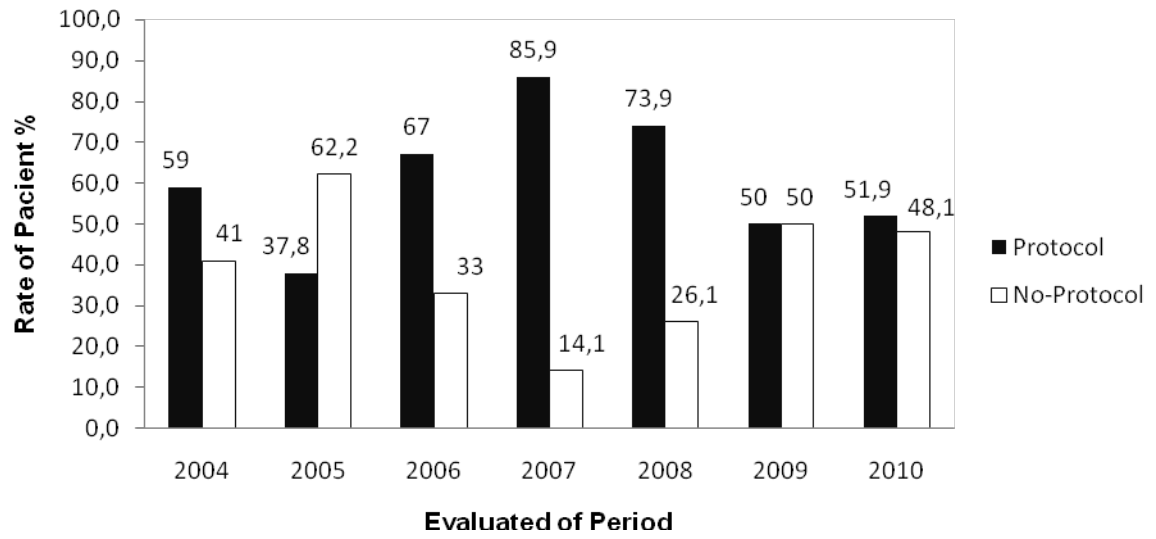
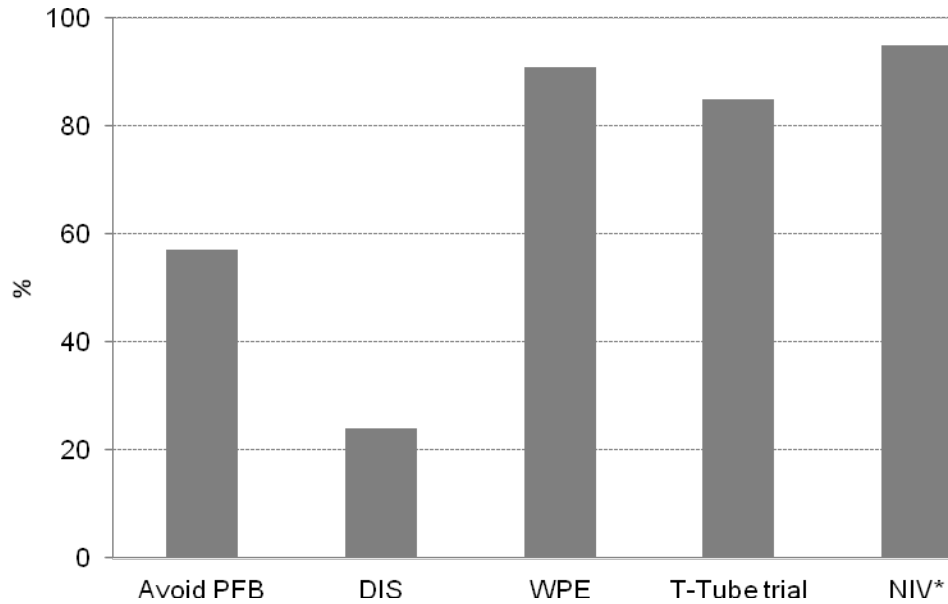
Figure 3: Adherence rate to the protocol

Figure 4: Histogram showing percentage (%) of step-by-step patient's attendant-physicians adherence to the protocol.



* Represents the percentage of patients with criteria for use NIV after extubation and use it.

Definitions of abbreviations: DIS = daily interruption of sedation, NIV = noninvasive ventilation, PFB = positive fluid balance, WEP = weaning predictor evaluation

8 CONSIDERAÇÕES FINAIS

Podemos observar que o sucesso no desmame da ventilação mecânica foi maior no grupo protocolo, mesmo com uma variação na aplicação do protocolo durante os anos de estudo. A adesão médica ao protocolo de desmame mudou durante os anos da pesquisa, bem como a implementação às diferentes etapas do estudo. Isso pode ter ocorrido por diferentes níveis de conhecimento médico e educação oferecidas à equipe do Centro de Terapia Intensiva (CTI) durante os anos. Algumas etapas do protocolo parecem ser mais atrativas ou de maior conhecimento médico. A implementação de uma nova abordagem requer um treinamento e uma educação constante na equipe que assiste o paciente para se tornar uma rotina na prática diária, sendo necessária uma revisão periódica de tempos em tempos na aplicação do protocolo, uma vez que a equipe assistencial pode mudar com o passar dos anos.

- O Protocolo deve ser organizado e fácil de ser implementado
- O Protocolo não é para substituir o julgamento clínico e sim complementá-lo;
- Mais estudos sobre o impacto do desmame baseados em protocolos são necessários para validar preditores de desmame usados em protocolos

9 PERSPECTIVAS FUTURAS

Este trabalho mostrou a necessidade do acompanhamento de perto da implantação de um protocolo de desmame da ventilação, sendo esta uma rotina aplicada até os dias de hoje. Uma vez que possa ocorrer mudança no quadro de pessoas que trabalham em uma CTI, se julga necessária a inclusão, e ou a manutenção e a educação em treinamentos periódicos obrigatórios com o corpo clínico da equipe assistencial, incentivando o uso do protocolo, pois mostrou-se eficaz na sua implantação.

10.LIMITAÇÕES DO ESTUDO

Estudo de coorte – Menor validação

Mudança na equipe assistencial durante os anos do estudo;

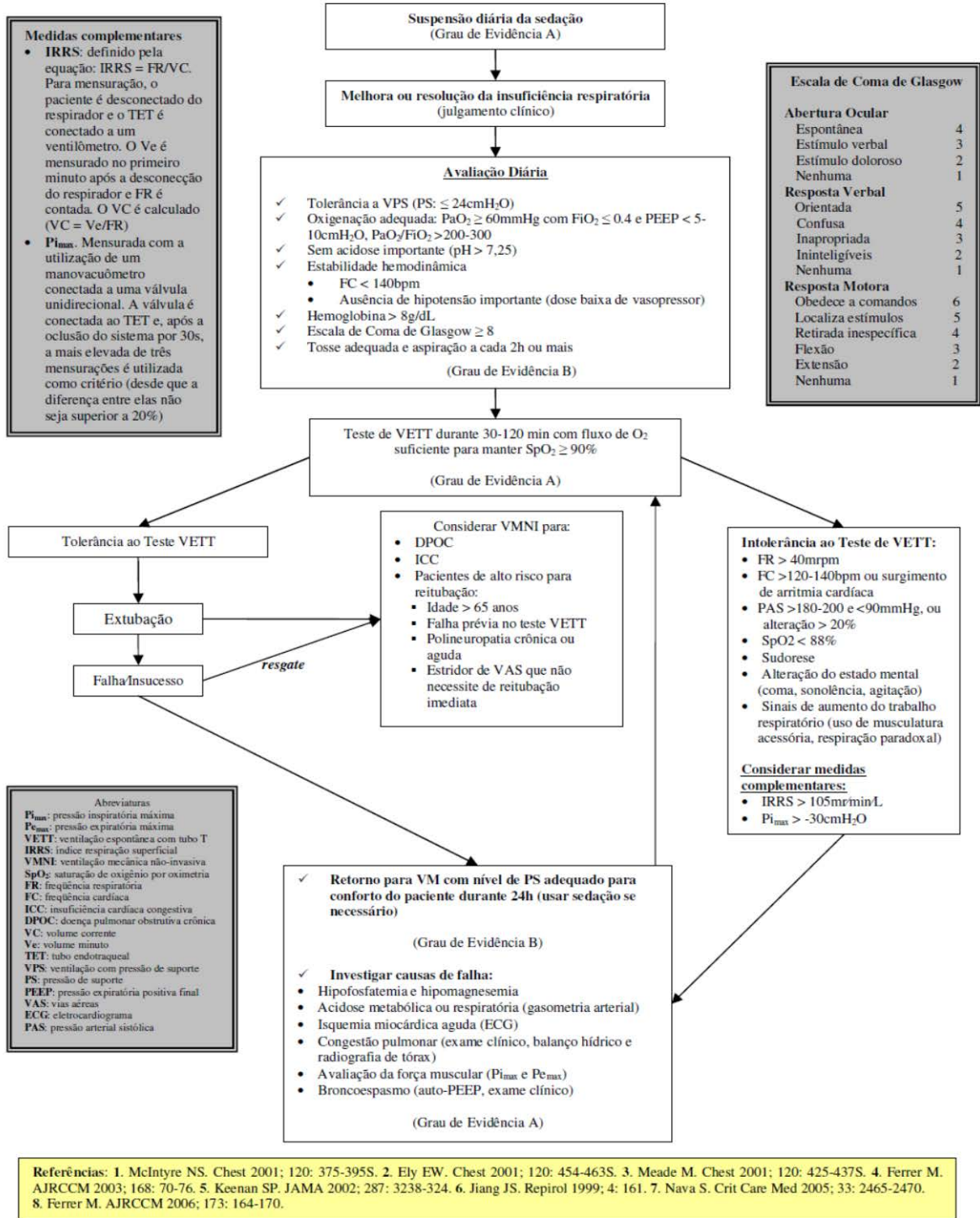
Dificuldade em exigir e administrar o uso de uma nova rotina na equipe assistencial;

CTI aberta, dificuldade em implantar novas abordagens

10 ANEXOS

ANEXO 1

Protocolo de Desmame da Ventilação Mecânica



ANEXO 2

Ficha de Preenchimento Protocolo de Desmame

Nome: _____ Prontuário: _____

Idade: _____ Sexo: M F APACHE internação: _____ Leito: _____

Data internação hospitalar: _____ Data internação CTI: _____

Data alta hospitalar: _____ Data alta CTI: _____

Tempo internação hospitalar: _____ Tempo internação CTI: _____

Óbito: N S Data óbito: _____ Motivo óbito: _____

Motivo da Internação no CTI

1. Pós-operatório
2. TEP
3. ICC
4. AVC
5. Sepsis
6. Sepsis respiratória
7. EPS
8. PCR
9. Asma aguda grave
10. DPOC descompensado
11. Politrauma
12. IAM
13. Pancreatite
14. Outro _____

Motivo da Ventilação Mecânica

1. Coma
2. DPOC
3. Asma
4. Pós-operatório
5. Doença neuromuscular
6. Conforto
7. BCP comunitária
8. BCP nosocomial
9. TEP
10. LPA / SARA
11. ICC/EAP
12. Outro _____

Comorbidades:

1. DPOC
2. HAS
3. Cardiomiopatia dilatada
4. Asma
5. DM
6. IRC
7. Corticoterapia
8. Doença neuromuscular
9. TEP
10. Cirrose
11. AVC
12. Neoplasia
13. Imunossupressão
14. Cardiopatia Isquêmica
15. Outro _____

VENTILAÇÃO PRÉ- EXTUBAÇÃO

Ventilador: Servo300 Servo900 Evita 2 Evita4 Outro: _____

Modo: A/C pressão A/C volume PS CPAP SMIV Outro: _____

PEEP: _____ P pico: _____ VC: _____ FiO₂: _____PaO₂/FiO₂: _____ / _____ = _____**Força muscular****respiratória**

	Pimax	Pemax
1º minuto VETT		
30º minuto VETT		

Data intubação: _____

Data extubação: _____ Hora: _____

APACHE extubação: _____ Glasgow: _____ Nº TET: _____

Gasometria	Na VM	30 minutos VETT
pH		
PaCO ₂		
PaO ₂		
HCO ₃		
SatO ₂		
EB		

VETT	1º min	30ºmin
Ve		
FR		
VC (Ve/FR)		
IRRS		
PA		
FC		
SpO ₂		

SINAIS DE MÁ TOLERÂNCIA VETT: _____

SINTOMAS: Dor: S N Desconforto: S N Dispneia:(avaliado por escala analógica-visual 0-10)

DROGAS EM USO:

Corticóide: N S Início: _____ Fim: _____

Opióides: N S Início: _____ Fim: _____

Bloqueador neuromuscular N S Início: _____ Fim: _____

Benzodiazepínicos N S Início: _____ Fim: _____

Outros: _____ Início: _____ Fim: _____

RAIO X TÓRAX:

Consolidações N 1 2 3 4

Infiltrado N 1 2 3 4

Derrame pleural N unilateral bilateral

Retorno a ventilação: N S Data: _____ Hora: _____

Extubação: Sucesso Falha

Motivo Reintubação:

1. Sinais de aumento do trabalho respiratório
2. Hipoxemia
3. Acidose respiratória
4. Retenção de secreções
5. Depressão do sensorio
6. Instabilidade hemodinâmica

Uso de VMNI (pós-extubação): S N Tempo: _____

EXAMES: Hematócrito: _____ Hemoglobina: _____ Sódio: _____ Potássio: _____

Magnésio: _____ Cálcio: _____ Albumina: _____ Fósforo: _____

BALANÇO HÍDRICO: 24h: _____ 48h: _____ PVC: _____

