Doutoramento Ciências de Enfermagem



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THE IMPACT OF NURSE-LED WEANING PROTOCOL ON THE OUTCOMES OF MECHANICALLY VENTILATED CRITICALLY ILL PATIENTS FATIMA MOHAMMED HIRZALLAH

INSTITUTO DE CIÊNCIAS BIOMÉDICAS ABEL SALAZAR





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Thesis application for the degree of Doctor of Nursing Sciences submitted to the Abel Salazar Institute of Biomedical Sciences (ICBAS) of the University of Porto.

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الحمد لله رب العالمين

"We can change our lives. We can do, have, and be exactly what we

wish."

Tony Robbin

For my mother with love

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Abstract

Intensive care unit (ICU) patients spend half of the total ventilator time on weaning. Prolonged mechanical ventilation is associated with adverse outcomes for critically ill patients: longer hospital stay and higher morbidity rate. Many studies support that ventilator-weaning protocols have positive outcomes in patients weaned by a defined protocol rather than usual care. Moreover, studies have reported that a weaning protocol administered by nurses leads to a reduction in the duration of mechanical ventilation and has a major effect on weaning outcomes. The aim of this doctoral dissertation is to determine the impact of nurse-led weaning protocol on outcomes of critically ill adult patients who received invasive ventilation compared to usual weaning care. This research project has three studies using a combined different methodological approach. A systematic review meta-analysis was conducted to synthesize the current best evidence for the effectiveness of weaning protocols led by nurses, with a total of 532 patients from three eligible studies that were included in the final review (Study I). A qualitative descriptive study (Study II) was conducted to elicit perceptions of nurses towards a nurse-led weaning protocol using two focus groups (one in each hospital) pre and post protocol application, following the same interview guide. The sample consisted of 13 nurses in both hospitals: pre-protocol (six nurses in the first group, and seven nurses in the second group), and 11 nurses post-protocol(five nurses in the first group, and six nurses in the second group). A quasi-experimental prospective study was conducted (Study III), in which a nurseled weaning protocol was applied over 13 months. A total of 68 adult patients (≥18 years) who were mechanically ventilated via endotracheal tube for \geq 24 hours, in multicenter ICU's in Palestinian hospitals were distributed in experimental group and control group. The nurse-led weaning protocol for the experimental group (n = 34patients) was matched with historical controls (1:1 matching) of retrospective data of UC weaning for the control group (n = 34 patients). The protocol was presented to the ICU nursing staff during a training session. The variables were evaluated before and after the intervention, explicitly: duration of mechanical ventilation, weaning time, ICU and hospital length of stay, and reintubation rate. The results highlighted that the nurse-led weaning protocol in a medical/surgical ICU significantly reduces the median duration of mechanical ventilation: 24 hours (IQR=30hrs) for the experimental group and 48 hours (IQR=48hrs) for the control group (P = .034). It also shows reduction in the median weaning time in the experimental group equalling 2 hours (IQR=2hrs) in comparison to 4 hours (IQR=3hrs) in the control group (P=.001); a decrease in the median duration of ICU length of stay as it was 5 days (IQR=5 days) for the experimental group and 7 days (IQR=6 days) for the control group (P = .03); and that nurse-led weaning significantly lowers reintubation rates: 3/34 (8.8%) in the experimental group and 11/34 (32.4%) in the control group. As a conclusion, a nurse-led ventilator weaning protocol had a positive impact on mechanically ventilated adult patients and had a major effect on weaning outcomes. Based on the findings of all studies included in this doctoral dissertation, we emphasize the proposition that the implementation of weaning protocol by nurses:(1) reduces duration of mechanical ventilation, (2) reduces weaning time, (3) reduces ICU length of stay, (4) lowers reintubation rates in critically ill adult patients, (5) is safe for patients, and (6) is accepted by all ICU health staff and viable for applicability among Palestinian ICU.

Key words: mechanical ventilation, ventilator weaning, protocol, critical care nursing

Resumo

Em doentes internados emUnidades de Cuidados Intensivos (UCI), metade do tempo de internamento deve-se ao desmame da ventilação mecânica. A ventilação mecânica prolongada está associada a desfechos adversos em doentes graves, com maior tempo de internamento e maior morbilidade. Vários estudos sustentam que os protocolos de desmame do ventilador têm resultados positivos em doentes que foram desmamados com um protocolo definido, em vez dos cuidados habituais. Por outro lado, há evidência de que um protocolo administrado por enfermeiros leva a uma redução na duração da ventilação mecânica e tem um efeito importante sobre os resultados do desmame. O objetivo desta tese de doutoramento é determinar o impacto de um protocolo de desmame da ventilação mecânica liderado por enfermeiros, nos desfechos de doentes adultos gravemente enfermos, que receberam ventilação mecânica invasiva, em comparação com o tratamento usual. Este projeto de pesquisa inclui três estudos, com recurso a abordagem metodológicas diversas. O Estudo lé uma revisão sistemática, com meta-análise, e foi realizada para sintetizar as melhores evidências sobre a eficácia dos protocolos de desmame do ventilador, liderados por enfermeiros, com um total de 532 pacientes, dos três estudos elegíveis que foram incluídos na revisão final. Um estudo qualitativo descritivo (Estudo II) foi realizado para identificar as perceções de enfermeiros em relação aos protocolos de desmame do ventilador, usando dois grupos focais (um em cada hospital) pré e pós-aplicação de protocolo, seguindo o mesmo guia de entrevista. A amostra foi composta por 13 enfermeiros em ambos os hospitais: pré-protocolo (seis enfermeiros no primeiro grupo e sete enfermeiros no segundo grupo) e 11 enfermeiros pós-protocolo (cinco enfermeiros no primeiro grupo e seis enfermeiros no segundo grupo). O Estudo III é um estudo prospetivo, quase-experimental, no qual um protocolo de desmame do ventilador foi aplicado durante 13 meses. Um total de 68 pacientes adultos (\geq 18 anos) que foram ventilados mecanicamente via tubo endotraqueal por \geq 24 horas, em multicêntrico UCI, em hospitais Palestinianos, e foram distribuídos em grupoexperimental e grupocontrolo. Os doentes do grupo de experimental, submetidos ao protocolo, (n = 34 pacientes) foram combinados com controles históricos (1: 1) de dados retrospectivospara o grupo controlo (n = 34 pacientes). O protocolo foi apresentado à equipe de enfermagem das UCI durante uma sessão de formação. As variáveis foram avaliadas antes e após a intervenção, nomeadamente: duração da ventilação mecânica, tempo de desmame, tempo de permanência na Unidade, tempo de permanência hospitalar, e taxa de reintubação. Os resultados evidenciaram que a intervenção, protocolo de desmame do ventilador, reduz significativamente a duração mediana da ventilação mecânica: 24 horas (IIQ = 30hrs) para o grupo experimental e 48 horas (IIQ = 48hrs) para o grupo controlo (P = 0,034). Também mostra redução no tempo médio de desmame no grupo experimental, 2 horas (IIQ = 2hrs) em comparação com 4 horas (IIQ = 3hrs) no grupo controlo (P = 0,001); uma diminuição na duração do tempo de permanência na UCI, que foi de 5 dias (IIQ = 5 dias) para o grupo experimental e 7 dias (IIQ = 6 dias) para o grupo controlo (P = 0,03); e que o

desmame assistido por enfermeiros reduz significativamente as taxas de reintubação: 3/34 (8,8%) no grupo experimental e 11/34 (32,4%) no grupo controlo. Concluindo, um protocolo de desmamedo ventilador liderado por enfermeiros teve um impacto positivo em pacientes adultos ventilados mecanicamente e teve um efeito importante nos resultados do desmame. Com base nos resultados dos estudos incluídos nesta tese podemos concluir que a implementação de um protocolo de desmame da ventilação mecânica, liderado por enfermeiros: (1) reduz a duração da ventilação mecânica, (2) reduz o tempo de desmame do ventilador, (3) reduz a permanência na UCI, (4) reduz as taxas de reintubação, (5) é seguro para os pacientes e (6) é aceitepelos profissionais de saúde e é viável para ser aplicável nas UCI, na Palestina.

Palavras-chave:, ventilação mecânica, protocolos; desmame do ventilador; enfermagem de cuidados intensivos

CHAPTER I - Introduction

1.1- Introduction to the study topic

Approximately 50% of intensive care unit (ICU) patients need mechanical ventilation (MV) (Topin et al., 2004). Prolonged MV is associated with adverse outcomes for critically ill patients; longer hospital stay and higher morbidity rates including ventilator associated pneumonia, ventilator-associated lung injury, and mortality (Blackwood et al., 2011; McConville & Kress, 2012; Roh et al., 2012). Patients in ICUs require advanced care and frequent monitoring (Blackwood et al., 2009). ICU patients spend half of the total ventilator time on weaning (Cederwall et al., 2014) Weaning from MV is challenging and requires expert knowledge and skill (Crocker, 2002). Weaning is defined as a process leading to the discontinuation of MV. The weaning process involves gradually reducing ventilator support while increasing the patient's control of breathing (Tingsvik et al., 2015). Ventilator management should aim to get the patient off ventilator support as rapidly as possible (Grap et al., 2003). Minimizing the duration of MV is an important consideration for all clinicians who care for critically ill patients. Evidence from clinical trials suggests that protocol-directed weaning consistently reduces duration of MV, reduces ventilator-associated complications, and reduces the rate of reintubation (McLean et al., 2006). Previous studies that investigated the effectiveness of a protocol for weaning from MV used the overall duration of MV as the primary outcome (Blackwood et al., 2009). Many studies supported that ventilator weaning protocols have a positive outcome and reduce weaning time in patients in comparison to usual care (UC) (Kollef et al. 1997; Roh et al., 2012). The main goal for using a weaning protocol is to provide a systematic approach to help patients reduce the length of stay (LOS) in the ICU by reducing the duration of MV and improving patient outcome (Blackwood et al., 2009; Grap et al., 2003). Therefore, the use of a protocol allows the staff to identify the earliest opportunity for a patient to breathing spontaneously, to optimize extubation timing and avoid both reintubation and overlong intubation, and to reduce weaning time (Fulbrook, 2004). There is also evidence that the involvement of nurses and respiratory therapists in this process is beneficial. Evidence-based appraisal of the literature supports that nurses and related health professionals adhere to protocols more closely than physicians, and that had a major effect on weaning outcomes, and reduced the duration of MV (Blackwood et al., 2011; Dries et al., 2004; Plani et al., 2013). Moreover, a recent systematic review (Hirzallah et al. 2018, in press) showed evidence that nurses-led weaning protocols reduce the duration of MV, weaning time, ICU LOS compared to physician-led UC without adverse effects; and that they are easy to implement, safe, and are accepted by the ICU health staff. The results of the actual research conducted in Palestine on the implementation of weaning protocol led by nurses demonstrated that the nurseled weaning protocol (NLWP) group showed a decrease in the median duration of MV, weaning time, and median duration of ICU LOS, and it has significantly lower reintubation rates compared to the UC group.

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The current study is unique because it is the first study of this kind to be conducted in Palestine. There are few studies that investigate the implementation of weaning protocols led by ICU nurses alone to guide weaning patients from MV. We believe this study provides further evidence that NLWP has a major impact on weaning outcomes. This is can be considered one of the innovative aspects of this doctoral dissertation.

1.2- Aims

• General aim

To develop and implement a NLWP and to evaluate its impact on critically ill patient outcomes

- Specific objectives:
- To synthesize the current best evidence for the effectiveness of weaning protocols led by nurses by answering the following question: Do weaning protocols led by nurses reduce the duration of MV, weaning time, ICU and hospital LOS, hospital mortality, rate of ventilator-associated pneumonia, and rate of reintubation in critically ill adult patients (≥18 years) that have had invasive MV compared to usual physician-led care? (Study I).
- 2. To identify nurses' perceptions toward NLWPs pre and post protocol implementation for mechanically ventilated adult patients in the ICU among Palestinian hospitals in a qualitative study, using focus groups (Study II).
- 3. To determine if a weaning protocol led exclusively by critical care nurses reduces the duration of MV, weaning time, ICU and hospital LOS, and reduces reintubation rate in critically ill adult patients (≥18 years) who receive invasive ventilation via endotracheal tube for ≥ 24 hours at the time of study enrolment, compared to physician-led usual weaning care in the ICU of multicenter among Palestinian hospitals (Study III).

1.3- Concepts definition

For the present study the following concept definitions are considered:

Critically ill patients are defined as those patients who are at high risk for actual or potential life-threatening health problems.

Critical care nurse: is defined as a licensed professional nurse who is responsible for ensuring that acutely and critically ill patients and their families receive the highest nursing care, according to the American Association of Critical Care Nursing.

Mechanical ventilation: is a method to mechanically assist or replace spontaneous breathing (Blackwood et al., 2009), through a positive or negative-pressure breathing device that can maintain ventilation and oxygen delivery for a prolonged period of time (Smeltzer et al., 2014).

Duration of mechanical ventilation is measured in consecutive minutes, with intubation or the establishment of an airway by means of an endotracheal tube as the first minute of MV, and extubation or the removal of the endotracheal tube as the last minute of MV (McLean et al., 2006). It is defined by Danckers et al. (2013) as the period from the day of endotracheal intubation until the day of discontinuation of MV.

The total duration of mechanical ventilation is the time in hours from initiation on MV to discontinuation (Blackwood et al, 2009).

Weaning is the process leading to the discontinuation of MV. Weaning from MV is the period of transition from total ventilatory support to spontaneous breathing (Blackwood et al., 2009). Another definition for the weaning process is reducing ventilator support and/or conducting tests to determine whether a patient can breathe on his/her own (Burns et al., 2014; Roh et al., 2012).

Weaning duration is the time from mechanical ventilator discontinuation to extubation (time of weaning readiness to discontinuation of MV) (Blackwood et al., 2009).

Weaning time is defined as the time from enrollment to successful discontinuation of MV, which means that weaning from the mechanical ventilator was initiated and the condition causing respiratory failure had been treated (Roh et al., 2012). The duration of MV and weaning is varied and depends upon the patient's clinical condition and progress (Blackwood et al., 2009).

Protocolized weaning is a complex intervention involving several components as defined by Blackwood et al. (2009). It is defined as a method of limiting the duration of invasive ventilation (Roh et al., 2012), that promotes a standardized assessment of each patient's readiness to wean as part of the daily assessment by the heath care professional.

1.4- Thesis outline

This doctoral dissertation focuses on the implementation of NLWP in the ICU in Palestinian hospitals in Nablus and Ramallah cities, Palestine. This topic is assessed from different viewpoints, using and combining different methodological approaches.

In chapter one, the study is briefly presented with the introduction highlighting the development of NLWPs. The chapter also provides general aims and specific objectives as well as concepts definition and the outline of the thesis.

In chapter two, the scientific and theoretical backgrounds of the study are discussed. The scientific background includes an overview of weaning from MV, conceptual definitions, methods and approaches to weaning, and the classifications of the weaning process. In terms of the theoretical background, the study integrates Benner's adapted theory to critical care's nursing role, through the major concepts of the Benner's model of nursing with focus on critical care nursing practice of using weaning protocols in ICUs and describing the nature of skill acquisition in critical care nursing practice. Benner's theory helps in providing valuable information about the role of nurses in the ICU and how to integrate using weaning protocols driven by nurses to the nursing theory in the context of critical care.

Chapter three reports on the methodological paradigm that is applied in this research project, namely: the type of the overall study and its justification, study design, methods applied to each specific study of this broader research project, data collection instruments, procedures, and ethical considerations.

Chapters four, five, and six present original studies detailed in the context of this research, which describe the findings of this research, as follows:

Chapter four is entitled "A systematic review of nurse-led weaning protocols for mechanically ventilated adult patients: a meta-analysis". This systematic review and meta-analysis aim to synthesize the current best evidence on the effectiveness of weaning protocols led by nurses in adult intensive care patients who were mechanically ventilated and have an endotracheal tube compared to UC - physician-led care. Three eligible studies with a total of 532 patients were included in the final review after retrieving 369 articles from electronic database such as CINAHL, PubMed, Scopus and the Cochrane Central Register of Controlled Trials. All studies provided a comprehensive description of the methodology. Results highlight that pooled data show statistically significant difference in favor of the NLWP for reducing the duration of MV, weaning time, ICU and hospital LOS. This review provides evidence in support of ICU nurses' crucial role and abilities to lead weaning off MV and have a positive impact on outcomes of weaning mechanically ventilated adult patients as well as the safety of the process.

In chapter five, we examine the development of the qualitative descriptive research

study entitled "Critical Care Nurses 'Perceptions Towards Nurse-Led Weaning Protocol From Mechanical Ventilation In Intensive care units in Palestine- A qualitative Study". The study aims to obtain an in-depth understanding of the perceptions of nurses toward NLWPs pre and post their participation in the implementation of the weaning protocol in ICUs among Palestinian hospitals. This was achieved using focus groups following the same interview guide, which was conducted concurrently with the quantitative study (pre and post protocol implementation). The main findings of this study were that ICU nurses hold a positive overall impression of and support the NLWPs in ICUs and find them viable for applicability among Palestinian ICUs. Themes represented that the weaning protocol led to the improvement of patient outcomes, prioritization of patient safety by reducing weaning trials, enhancement of interprofessional competency, in addition to barriers to nurse-led weaning.

Chapter six presents the quantitative study, entitled "The impact of critical care nurseled weaning protocol on outcomes of MV for critically ill patients among Palestinian hospitals". The main objective of the prospective quasi-experimental study is to determine if the weaning protocol led exclusively by critical care nurses reduces the duration of MV, weaning time, ICU and hospital LOS, and reintubation rate in critically ill adult patients (age ≥ 18 years) who receive invasive ventilation via an endotracheal tube at the time of study enrolment compared to UC among ICUs of Palestinian hospitals. Our results demonstrate that the NLWP group showed a decrease in median duration of MV, shorter weaning time, decrease in median duration of ICU LOS, and significantly lower reintubation rates compared to UC group.

The last chapter, chapter seven, is devoted to the general discussion and major conclusions of this research, pinpointing its limitations, strengths and implications for clinical practice, and future research.

1.5- References

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CHAPTER II - Scientific and Theoretical Background of Nurses-Led Weaning Protocol

- 2.1- Overview of mechanical ventilation
- 2.2- Weaning from mechanical ventilation
- 2.3- Protocol led weaning

2.4- Integration of Benner's theory to nurse-led weaning protocol for mechanically ventilated adult patients

2.5-References

In this chapter, we approach the theoretical and scientific background of our research project, starting with an overview of the weaning from MV. This includes conceptual definitions, methods of weaning, and approach to weaning, and the classifications of the weaning process. In addition to that, we present the theoretical background of this study by integrating Benner's adapted theory to critical care nursing role, through the major concepts of the Benner's model of nursing, focusing on critical care nursing practice of using weaning protocols in ICUs and describing the nature of skill acquisition in critical care nursing practice. Benner's theory helps in providing valuable information about the role of nurses in the ICU and how to integrate the use of weaning protocols driven by nurses to the nursing theory in context of critical care. We aim to develop the arguments by introducing a weaning protocol led by nurses to expert nurses using Benner's model. This chapter provides a new vision about the role of intensive care nursion about the value protocols for critically ill patients integrated to nursing theory.

2.1- Overview of mechanical ventilation

Mechanical ventilation

Mechanical ventilation is a method to mechanically assist or replace spontaneous breathing. MV is a therapy designed to support the respiratory system until the underlying disease or indication for MV is resolved (Sole et al., 2013). Most of ventilatory support requires artificial ventilation (invasive MV), but ventilator support may also be applied without artificial ventilation and is called noninvasive MV.

Classification of ventilators

Mechanical ventilators are classified according to the method by which they support ventilation. The two general categories are negative-pressure and positive-pressure ventilators. The most common category in use today is the positive-pressure ventilator (Smeltzer et al., 2014). MV utilizes several separate systems for ventilation referred to as the mode. All modes fall into one of three categories; volume-cycled, pressure cycled, spontaneously cycled (Smeltzer et al., 2014).

The team caring for a ventilated patient should always be planning for how the patient will be weaned or "liberated" from the ventilator. Another term for liberation is discontinuation of ventilator support. The process leading to discontinuation of MV is known as weaning. The process of weaning of critically ill adult patients from MV refers to the gradual discontinuation of MV (McLean et al., 2006).

2.2- Weaning from mechanical ventilation

Weaning from MV represents the period of transition from total ventilatory support to spontaneous breathing (Blackwood et al., 2009). During weaning, the work of breathing is transferred from the ventilator to the patient. Conceptually, weaning from MV includes both the assessment of a patient's readiness to breathe independently and the systematic reduction of ventilatory support (Grap et al., 2003, p. 455). The period of transition may take many forms, ranging from abrupt withdrawal to gradual withdrawal from ventilatory support (Blackwood et al, 2009). It is important to discontinue MV as soon as patients can breathe independently (Blackwood et al., 2009). A philosophy of weaning is that weaning should be considered as a daily reduction of ventilator support (where possible) to avoid over and under ventilation with the preservation of muscle strength without causing fatigue (Crocker, 2002). Thus, weaning should be planned as soon as the patient begins with MV. It is vital that the time on a ventilator is as short as possible to reduce suffering and the risk of complications (Tingsvik et al., 2015).

Methods of weaning

There are several options or weaning methods for decreasing ventilatory support, including :i) intermittent T piece trials involving short time periods of spontaneous breathing through a T piece circuit while the patient is still intubated; ii) synchronized intermittent mechanical ventilation (SIMV) involving gradual reductions in the

ventilator rate by increments of 1 to 4 breaths/min; iii) pressure support ventilation (PSV) involving the gradual reduction of pressure by increments of 2 to 6 cm H2O; iv) spontaneous breathing through a ventilator circuit with the application of continuous positive airway pressure (CPAP); or combinations of these and newer options such as bi-phase assisted pressure (BIPAP) (Blackwood et al., 2011, Smeltzer et al., 2014).

Approach to weaning

Approach to weaning from MV is a two-step process:-

Step 1- Readiness testing 'Readiness to wean' criteria	Weaning parameters assessment (wean screen), readiness testing: during readiness testing, objective clinical criteria or parameters are evaluated to determine whether a patient is ready to begin weaning (ready to tolerate MV discontinuation).
Step 2-perform weaning trial by gradual reduction of ventilator support	Perform weaning trial: It may involve either an immediate shift from full ventilatory support to a period of breathing without assistance from the ventilator, which is called the initial trial (e.g, a spontaneous breathing trial [SBT]), or a gradual reduction in the amount of ventilator support. The initial trial should last 30 -120 minutes . Pressure support or assist-control ventilation modes should be favored in patients failing an initial trial/trials.

Weaning is based on patient readiness determined by objective and physiological criteria. The list of physiological criteria will achieve a holistic assessment of patients' readiness to wean and acknowledge the important and complementary role of the nurse in the weaning process (Blackwood, 2000). Furthermore, daily SBTs are superior to gradual reductions in ventilatory support (i.e., gradual reduction in synchronized mandatory ventilation or pressure-support ventilation (Grap et al., 2003).

Weaning is just one example of the complexity of managing ICU patients (White et al., 2011), and demands knowledge of the respiratory system, physiology, pathophysiology, pharmacology, and current technology (Tingsvik et al., 2015). Evidence suggests that clinical assessments (respiratory pattern, cardiovascular response, comfort/anxiety, oxygenation) are better predictors of success complex weaning parameters (Grap et al., 2003). Weaning is an example of complex ICU patient management that is reliant on integrating information from advanced technologies with patient data (Galvin, 2010). The transition from mechanical support to spontaneous breathing is considered a critical period for many mechanically ventilated patients, and physical and psychological readiness of the patient is important in determining a successful weaning outcome (Blackwood et al., 2000). A variety of weaning strategies and approaches have been used to assess weaning readiness and to reduce ventilatory support with various degrees of success (Grap et al., 2003).

Classifications of weaning according to the duration of weaning process

Weaning is classified into three groups based on the difficulty and duration of the weaning process as follows (Jeong et al., 2015):

Simple weaning: patients who proceed from initiation of weaning to successful extubation on the first attempt without difficulty.

Difficult weaning: patients who fail initial weaning and require up to three SBTs or as long as 7 days from the first SBT to achieve successful weaning.

Prolonged weaning: patients who require more than three SBTs or >7 days of weaning process after the first SBT.

Most intubated patients (69%) can be weaned easily (simple weaning patients) as they successfully pass the initial SBT and are successfully extubated on the first attempt, and (31%) are difficult-to-wean patients who fail the first SBT or extubation (Jeong et al., 2015). Patients are classified as successfully weaned if they were able to breathe unassisted for 48 hours at their first SBT (Roh et al., 2012). Patients who have difficulty in discontinuing MV frequently require longer hospital stay and generally have higher morbidity and mortality rates (Blackwood et al., 2009).

Weaning failure is defined as the failure to pass a SBT or the need for reintubation within 48 hours following extubation as predicting success is important to reduce rates of reintubation (Blackwood et al., 2009). Premature discontinuation of MV can contribute to unsuccessful extubation; requiring reintubation. Reintubation potentially induces harmful complications associated with airway trauma, gastric aspiration, acute lung injury, cardiovascular compromise, and hypoxia (Blackwood et al., 2009).

2.3-Protocol led weaning

Protocolized weaning is a detailed intervention as defined by Blackwood et al. (2009). A Weaning Protocol promotes a standardized assessment of each patient's readiness to wean as part of the daily assessment by heath care professionals. Weaning protocols are generally based on three components: readiness to wean criteria, guidelines for reducing ventilator support, and extubation criteria; however, the criteria and the content of the guidelines may vary and not all protocols include extubation criteria (Blackwood et al., 2009; 2011). Weaning protocols provide a uniform method of practice in the area of weaning (Blackwood et al., 2007). Protocols are based on the principle that the collective knowledge of a group (Blackwood et al., 2009) and the common goal of all ICU team members involved in caring for mechanically ventilated patients is successful weaning from ventilatory support (Fulbrook et al., 2004). Therefore, there is an increased interest in developing weaning protocols that provide structured guidelines and deliver more consistent practice in ICUs (Blackwood et al., 2009). The quality of nursing is a significant factor in the weaning process, a key point when many units are finding the number of qualified nursing staff is being reduced.

2.4- Integration of Benner's theory to nurse-led weaning protocol for mechanically ventilated adult patients

Nursing theories provide inspiration for nurses in their clinical practice by describing how to meet needs, enhance wellness, and respond to clients as whole persons. Patricia Benner is one of many theorists who have considered the phenomenon of care as central to the philosophy of nursing (Allligood, 2014). Benner's theory links the concepts and assumptions that underpin the theoretical foundation and interconnect nursing practice, education, research, and management within a framework of logical organization aiming at skill acquisition. The context of the theory usage is described extensively as a support for the career development in critical care nursing. Benner's theory and the concept of reflective practice have been applied to improve the development of knowledge, professional growth, and innovative changes within the nursing profession in the context of critical care. We suggest that Benner's model provides for a relational approach that is congruent with the philosophy of critical care nursing. We aim to develop the arguments by introducing a weaning protocol led by nurses to expert nurses by utilizing Benner's model theory.

Nursing involvement in weaning has increased over the past two decades with the introduction of weaning protocols. The effect of weaning protocols may be moderated by contextual factors and no study has identified harm associated with nursing involvement in the weaning process (Rose et al., 2011). ICU nurses can gain expertise in using weaning protocols through education and clinical training, as weaning patients from ventilators requires education and clinical experience in holistic nursing (Heath, 2001). By comparing the value base of our practice against extant nursing theory, we can discover new opportunities for teaching and learning about what it means to be an advanced critical care nurse. Critical care nurses play a central role in helping ICU patients' gradual shift in care focus as the disease progresses, and in developing weaning plans with patients (Chrocker, 2009). Nursing, like other applied medical disciplines, is complex; the clinician must make critical decisions in response to changes in the patient's status and the nature of their clinical condition over time (Benner, Tanner & Chesla, 2009). Patients in critical care units are some of the most complex cases and complicated medical situations (Galvin, 2010). The ICU nurse is in a unique position for adopting holistic approaches to weaning, and such procedures require teamwork and consideration of all the factors that could influence the outcome of the weaning process (Mårtensson & Fridlund, 2002). Thus, employing expert nurses to lead the weaning protocol is crucial, as demonstrated in this chapter.

-The Benner's model of nursing and skill acquisition in critical care nursing practice

The model of skill acquisition (Dreyfus & Dreyfus, 1980; Dreyfus& Dreyfus, 1986) that Benner applied in her work From Novice to Expert (1984a); in which she adapted the Dreyfus model to clinical nurses' practice. In applying the model to nursing, Benner noted that "experience- based skill acquisition is safer and quicker when it rests upon a sound educational base" (Allligood, 2014, p. 122).

Benner's model is situational and describes five levels of skill acquisition and development, ranging from novice to expert; (1) Novice, (2) Advanced Beginner, (3) Competent, (4) Proficient, (5) Expert (Alligood, 2014, p. 124):

Level 1, the **Novice** nurse has no background experience of the situations in which he or she is involved.

Level 2, the **Advanced Beginner** nurse demonstrates a marginally acceptable performance. The advanced beginner nurse has enough experience to grasp aspects of the situation.

Level 3, the **Competent nurse** advises new rules and reasons procedures for a plan, while applying learned rules for action on the basis for relevant facts of that situation. For the Competent nurse, considerable conscious and deliberate planning helps determine which aspects of the current and future situations are important, and which can be ignored.

Level 4, the **Proficient nurse** at this level demonstrates a new ability to see the changing relevance in the situation, including recognition and implementation of skilled responses to the situation as it evolves. They demonstrate increased confidence in their knowledge and abilities (Benner et al., 2009). The proficient stage is a transitional stage into expertise (Allligood, 2014, p.125).

Level 5, the **Expert nurse** has an intuitive grasp on the situation and is able to identify the region of the problem without losing time considering a range of alternative diagnosis and solutions. The Expert nurse can recognize pattern on the basis of deep experiential background expertise.

- The integration of Benner's Model into advanced nurses using weaning protocols for intensive care patients

The most important aspects of expert in practice encompass: (1) clinical grasp and response-based practice, (2) embodied know-how, (3) seeing the "big picture," and (4) seeing the unexpected (Allligood, 2014, p.122). By using these aspects, we attempt to help ICU nurses to become experts in weaning patients, through getting more experience in the weaning process by using protocols for weaning mechanically ventilated patients in the ICU during clinical training and education. That is to improve their skill performance and having a good clinical grasp. Each of these aspects is

related to each other and is related to practice.

1-Clinical grasp and response-based practice

The aspects of clinical grasp include: responsiveness, understanding the immediate past, present, and immediate future, responding to both the clinical and human dimensions, and close linkages between understanding, action, and outcomes (Benner et al., 2009, p.145). Nurses practicing at the expert level are able to read the patient and respond instantly. This ability to read the patient's responses allows the nurse to determine what the patient's status can tolerate and what the appropriate intervention to offer is (Benner et al., 2009). This is supported by a recent study that found in each of Australia and New Zealand nurses frequently independently responsible for manipulation of ventilator settings titrated to physiologic parameters in ICU organizational characteristics have been noted as key contributors to ICU (Roh et al., 2012). Practical grasp reflects the skill of observing practical manifestations of changed physiological states and patient responses as well as engaging in practical reasoning (Benner et al., 2009). Clinical reasoning in transitions and the recognition of changing relevance are perceptual skills that assist in identifying significant clinical problems. Understanding the clinical grasp aspect within the Benner model means the nurse's clinical grasp includes understanding of the patient's situation. Through experience, the nurse knows what to expect in this patient's recovery.

Expert nurses are most likely to give the clearest account of a clinical situation based on their maximum grasp of clinical situations. The difference between proficient nurse and expert nurse is that the proficient nurse is characterized by engaged practical reasoning, which relies on mature and practiced understanding as well as a perceptual grasp of distinctions and commonalities in particular situations. On the other hand, the expert nurse knows what to anticipate and how to prepare for possible issues and problems compared to the nurse at the proficient level who still has to think about what to do (Benner et al., 2009). The proficient stage most likely will lead to expertise with additional experience (Benner et al., 2009). That is because once the nurse begins to see changing relevance, a current clinical situation can be seen in terms of a past clinical situation complete with all its sense of salience, thus enabling a higher-level skill of perception. According to Roh et al. (2012), a study for a weaning protocol administered by critical care nurses found that ICU nurses are able to respond more rapidly to changing patient status by making suitable adjustment for respiratory parameter of FIO2, PEEP, and inspiratory pressure, that led to rapid weaning and more rapid responses. This is consistent with Benner et al. (2009) that showed that nurses actively interpret the direction of the change and keep track of what can be ruled in and ruled out. Clinical grasp and clinical response are inextricably linked. For the expert nurse, having a good clinical grasp means "knowing what actions are appropriate" (Benner et al., 2009, p.148). Through education and use of the protocol, nurses have gained comprehensive and valuable knowledge of respiratory assessment and mechanics that allows them to actively contribute to good outcomes for patients (Grap et al., 2003). With experience, the nurse notices a shift in her ability to notice what is important. The nurse no longer has the level of anxiety about the consequences of what she might leave out, because she has more confidence in her ability to notice the important things (Benner et al., 2009).

2-Processing embodied know-how:

Skilled embodied know-how is crucial, knowing what to do and when to act (Benner et al., 2009). Response-based practice implies the skilled know-how to respond to the concrete demands of the situation. By being fully involved in the situation, nurses can know the patients and their pattern of responses and follow these responses to modify their own approaches (Benner et al., 2009). Embodied skills are the kind of skilled performance that is linked with judgment and is a form of knowing. The skilled performance of difficult technical tasks requires a good clinical grasp that comes only with practice (Benner et al., 2009). A study by Crocker & Scholes (2009) found that knowing the patient is dependent on time spent with the patient, intimacy with the patient, and the nurse's previous experience of caring for patients. The powers of understanding in the situation and the nature of experiential learning can be articulated and valued in the narratives. Based on Crocker's (2002) findings that knowing the patient is considered one of the important factors in the weaning process, that nurses can read the cues of the patient and detect early signs of fatigue, discomfort, and anxiety before physiological changes have been noted. Thus, ICU nurses who maintain a near continuous presence at the bedside may be best positioned to titrate ventilator settings in response to changes in physiologic parameters (Rose et al., 2011). Blackwood (2000) emphasizes that the assessment of readiness for weaning can only be recognized by bedside nurses and acknowledges the significant role of the nurse in the weaning process. Knowing the patient facilitates successful weaning and could improve patient outcomes by shortening the LOS for patients in the ICU (Crocker & Scholes, 2009). Consequently, there is a direct link between experience and confidence and successful weaning outcomes, thus knowing the patient requires continuity of care and expertise (Crocker & Scholes, 2009). Use of a nurse-directed weaning protocol may increase nurses' knowledge and sense of autonomy (Blackwood et al., 2007; Grap et al., 2003). Studies have shown the utility of nurse involvement in ventilator decision making is reliant on appropriate knowledge and skills to manage ventilation (Rose et al. 2011). Nurse-directed protocolized weaning has the capacity to produce positive benefits for patients. Caring science plays a prominent role in articulating a knowledge foundation and research-based descriptions of how spatiality, embodiment, inter-subjectivity and temporality are experienced by patients. Caregivers and families can serve as a directional knowledge base for critical care.

3-Seeing the big picture

Seeing the big picture is a character of expert nurses. It means seeing what else is happening in the clinical situation or on the clinical unit. The big picture for the expert nurse goes beyond the immediate clinical situation typical of the competent and proficient level of practice. Expert nurses have an expanded "peripheral vision," sensing the needs of other patients in the unit and the capabilities of nurses assigned to care for them and recognizing when greater skillful practice in seeing and understanding a whole clinical situation is required (Benner et al., 2009). This reflects the skill of seeing practical manifestations of changed physiological states and patient responses as well as engaging in practical reasoning about this transition (Benner et al., 2009). Blackwood (2000) found weaning to be based on patient readiness determined by objective, physiological, and psychological criteria, and that the physiological criteria only will not achieve a holistic assessment of patients' readiness to wean, but the complementary role of the nurse in the weaning process is also important. Another study found that more frequent ventilator-dependent patients generally remain in ICUs as they require advanced care and frequent monitoring (Blackwood et al., 2009). Bedside screening for ventilator weaning should be performed daily, therefore the nurses have information about the patient that physicians do not have, and they could then offer alternative approaches to weaning. Nurses are the ones who are prepared to "see" certain anticipated changes in patients, they are also best prepared to notice when these changes do not occur (Benner et al., 2009, p.127). Effectiveness of protocoled-weaning appears to be influenced by existing ICU working practices (Blackwood et al., 2005). Critical care nurses should stop looking for what is narrowly defined as the 'science' of weaning and concentrate on the art (Crocker, 2002).

4-Seeing the unexpected

Nurses practicing at the expert level have mature practical knowledge about what to expect of particular patient populations. This transformation in performance is noted as seeing changing relevance at the proficient level. At expert level, this ability continues to develop, and the practitioner gains competence and satisfaction from seeing the unexpected. Nurses can take a stand on the unexpected, for what the patient needs and wants (Benner et al., 2009) .These possibilities depend on the nurse knowing the patient and on patient-nurse relationship (patient-centered care); thus, the use of weaning protocols does not concentrate just on the physiological responses of the patient, weaning must be patient- centered and nurses need to understand the psychological aspects of weaning (Crocker & Scholes, 2009). Benner et al. (2009) explored in her model the nurses' actions and found that they are continuously examined and modified on the basis of the patient's responses rather than an abstract theoretical model of probability assessment. Crocker (2002) mentioned in her study that successful weaning, particularly of the difficult-to wean patients, requires great skill and underpinning knowledge. Despite the insufficient

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evidence base, to date nurses can use their expertise and nursing skills to develop patient-centered weaning plans that engage patients and utilize the skills of the whole multidisciplinary team (Crocker & Scholes, 2009). The protocol has increased nurses' direct involvement in the decisions related to patients' care and has provided an additional avenue for communication with the healthcare team (Grap et al., 2003; Roh et al., 2012). Findings indicated that interprofessional collaboration was the predominant model for decisions about MV weaning, and nurses generally had a reasonable influence on decisions made (Rose et al., 2011). Critical care nursing which has excellent practice can gain advanced clinical knowledge through the caring relationships with particular patients from experience with many persons in similar situations (Crocker & Scholes, 2009). In this aspect we can see that knowing and reading the patient well allows the expert nurse to notice when the patient has slight changes in clinical and human possibilities. Through this process, the nurse comes to understand the patient, gaining insight into his priorities and discovering his health goal.

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CHAPTER III - Methodology

- 3.1- Methodological paradigm
- 3.2- Aims
- 3.3- Research methods
- 3.3.1- Data collection methods: Eligible participants, study design and methods,

data analysis, and data collection instruments

- 3.4- Ethical considerations
- 3.5- References

In this chapter, detailed information is presented about the methodological designs that were applied in our research project. Following the description of the methodology paradigm, we present a concise explanation on the type of the overall study and it is justification, study design, methods applied to each specific study of this broader research project, data collection instruments, procedures, and ethical considerations. The following chapters will describe in detail the specific information about each study.

3.1- Methodological paradigm

We emphasize the need to develop interventions such quasi-experimental studies in nursing (NLWP) given its paucity. From a methodological point of view, this can be considered one of the innovative aspects of this doctoral dissertation. Therefore, this study focuses predominantly on quantitative paradigm in which some qualitative measures are included to provide a better comprehension yielding to the quantitative investigation (Figure 1. study methodological design). By conducting a combination of both quantitative and qualitative approaches, more information is obtained to particularly understand a specific phenomenon. This combination allows a wider vision of reality and understanding of the complexity of human experience. Further details on each specific study integrated in this project will be provided in each corresponding chapter.



Figure 1. Study methodological design

Thesis process:

The thesis process comprised of a six-step process:

Step one: Systematic review meta-analysis.

Step two: Nurses' perceptions toward NLWP (pre-protocol implementation) among ICUs in Palestinian hospitals by qualitative research using focus group design.

Step three: Protocol development (producing the weaning protocol).

Step four: Training session for the weaning protocol.

Step five: Implementation of the protocol.

Step six: Evaluation of the protocol by assessing nurses' perceptions toward NLWP (post-protocol implementation) among ICUs in Palestinian hospitals, using focus group design following the same interview guide.

In the **first step**, we conducted a systematic review meta-analysis study of appraisal of published research studies in order to synthesize the current best available evidence for the effectiveness of weaning protocols led by nurses compared to UC- physician-led weaning care.

In the **second step**, a qualitative research study was conducted to assess the ICU nursing staff perceptions toward NLWP (pre-protocol implementation) using focus group design. A focus group was formed in which the group members were encouraged to talk freely in order to obtain an in-depth understanding of nurses' perceptions and initial thoughts on hearing the term 'weaning protocol' and 'nurse-led protocol'. Also, to obtain their approval and acceptance of NLWP in ICUs of hospitals in Palestine.

The third step is the protocol development (producing the weaning protocol). The weaning protocol was developed, then modifications needed were made to transfer the NLWP into practice. We developed the weaning protocol through gathering information. First, we collected baseline data by recognizing routine clinical practice of UC of weaning (non-protocolized) in Palestinian hospitals and reviewing hospital charts by health information system (HIS) at hospitals to find out what weaning processes have been used. Second, to set our weaning criteria, we conducted a systematic review (Hirzallah et al., 2018, in press) to synthesize the current best evidence for the effectiveness of weaning protocols led by nurses compared to UC of weaning to establish what exactly our criteria should be based on the evidence from literature and to support this study. We searched databases from the largest sources of nursing and allied health journals. This consisted of a literature search to see exactly how much research had been carried out and what the findings of that

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research were about NLWP. Weaning protocol of this study was based on appraisal of literature of our systematic review of three previous studies (Hirzallah et al., 2018, in press). The review found that the most common weaning methods used in protocols included SBT with CPAP for patients who satisfied the eligibility weaning criteria for more than 24 hours (duration of SBTs ranged from 30 to 120 minutes through a ventilator circuit). Based on that we adopted Danker et al.'s (2013) study weaning protocol that used the most common of weaning methods for its weaning protocol.

Third, to ensure the content validity of the protocol, a panel of experts (anesthetist, intensivist, critical care nursing) at Palestinian hospitals was convened to provide constructive feedback on the quality of the action and objective criteria to evaluate each object. The panel provided information about the representativeness and clarity of each object. In addition, the expert panel offered concrete proposals for improvement of the measure, and then we completed the final modifications on the weaning protocol. The evaluation panel exhibited enthusiasm towards the study, and the anesthesiologist accepted and approved the nurse-led protocol of weaning in the ICU. All the members of the health team supported and encouraged the author to go through with this study, and concluded that implementing this protocol is justified to meet the needs of hospitals, especially considering the shortage of physician consultant staff and the critical state of Occupation in Palestine. That in addition to improving ICU nurses' professional competence and developing nursing ability to promote patient outcomes. Upon the approval of the protocol from the anesthesiologists and intensivist in clinical practice, a quasi-randomized controlled study was designed. The flow chart of weaning protocol was designed with the cooperation of the head nurse of the ICU at Rafidia Hospital, in order to illustrate the application of the weaning protocol for ICU nursing staff. It took the form of a color-coded flow chart that made it easier for the staff to follow. The criteria we used was deemed to be simple, easy, and practical to implement the protocol to achieve a successful liberation from MV.

The **fourth step** comprised of the training sessions on the weaning protocol. The protocol was presented to the ICU healthcare staff during a 2-week training period (twice a week, two hours per session) in both hospitals. They were trained on the weaning protocol, which included training programs before the start of the study. All nurses who are involved in the implementation of the protocol participated in the education program. There was also a medical entry in which we asked for a senior doctor to join us. Despite this being a nursing initiative, the medical intervention was important. Therefore, a multi-professional group of staff from different levels of experience and knowledge that represents the entire unit was formed. We educated the staff on how to follow the weaning protocol. This was carried out by presentations to staff nurses in the unit and ensuring they understood how to use the flowchart of protocol that was designed in order to illustrate the application of weaning protocol for ICU nursing staff. It also enabled them to ask questions that helped team members challenge the current practices and give nurses more autonomy over the weaning

process. Approval for the use of the flowchart for weaning protocol was obtained from the consultant anesthetist, and copies of the protocol were laminated and fixed to the chart table at each bed in the ICU. A pilot period of one month was provided, in order for nurses to become familiar with the protocol and the implementation. Patients entered the protocol when their underlying indication for MV has resolved or significantly improved according to predetermined protocol entry criteria. At the beginning of the study, the protocol was initiated under physician supervision, but driven by the nurses, who evaluated each patient for weaning, SBT, and extubation each morning. The nursing staff who were responsible for the actual weaning of the patient. Later, the adherence for the protocol was improved and the nurses started leading the protocol independently based on their assessment of patients. The NLWP was subsequently introduced into an intervention group of a total of 34 adult patients (Rafidia Hospital n=19, Ramallah Hospital n=15). During the implementation of the protocol, we met the health team to review the progress, and decided if the study was going well, and if we need to make any adjustments to the guidelines. A 'step-by-step' approach to developing and implementing the protocols was outlined.

Once the first four steps were completed, we started the next step. The **fifth step** was to implement the weaning protocol by nurses. We adopted a quantitative study design- a prospective quasi-experimental study since it was intended to determine the effectiveness of the weaning protocol implemented exclusively by critical care nurse on outcomes of critically ill patients for a period of approximately 13 months. We highlighted the need to develop nurses' role using a weaning protocol intervention; to increase awareness of weaning protocol among ICU nurses; and how the weaning protocol contributes to decrease duration of MV, weaning time, and the reintubation rate.

In the **sixth step**, once data had been collected after the intervention (weaning protocol), we developed a focus group post protocol implementation. The purpose of the focus group is to identify nurses' perceptions toward nurse directed weaning protocol in order to understand their perceptions and experience after their participation in the implementation of the protocol and to evaluate the weaning protocol.

3.2- Aims

• General aim

To develop and implement NLWP and to evaluate its impact on critically ill patient outcomes.

- Specific objectives:
- To synthesize the current best evidence for the effectiveness of weaning protocols led by nurses by answering the following question: Do weaning protocols led by nurses reduce the duration of MV, weaning time, ICU and hospital LOS, hospital mortality, rate of ventilator-associated pneumonia, and rate of reintubation in critically ill adult patients (≥18 years) that have had invasive MV compared to usual physician-led care? (I).
- 2. To identify nurses' perceptions toward NLWP pre and post protocol implementation for mechanically ventilated adult patients in the ICU among Palestinian hospitals in a qualitative study, using focus groups (II).
- 3. To determine if a weaning protocol led exclusively by critical care nurses reduces the duration of MV, weaning time, ICU and hospital LOS, and reduces reintubation rate in critically ill adult patients (\geq 18 years) who receive invasive ventilation via endotracheal tube for \geq 24 hours at the time of study enrolment, compared to physician-led usual weaning care in the ICU of multicenter among Palestinian hospitals (III).

3.3- Research methods

3.3.1-Data collection methods

All the methods utilized in this research project are described, in detail, in the different studies presented in Chapters IV, V, and VI; however, we will present a brief explanation of the methods for each study as follows: Eligible participants, study design and methods, data analysis, and data collection instruments in studies I-III as described in Table1.

	Study I Systematic review meta-analysis	Study II Focus group	Study III Quasi-experiment
Eligible participants (Study popu- lation Demographic data)	532 patients in three studies of adult patients (aged ≥18 years) who were mechanically ventilated and had an endotracheal tube in the ICU were included in the systematic review and meta-analysis study	24 ICU nurses Two focus groups, one in each hospital: one for Ramallah nurses and one for Rafidia nurses (pre-protocol, and post- protocol) Pre-protocol focus group: 13 nurses were interviewed in both hospitals (six nurses in the first group (Ramallah nurses), and seven nurses in the second group (Rafidia nurses). Post- protocol focus group: 11 nurses were interviewed in both hospitals: five nurses in the first group (Ramallah nurses), and six nurses in the first group (Ramallah nurses), and six nurses in the first group (Ramallah nurses), and six nurses in the second group (Rafidia nurses). Two nurses were unavailable because of the rotation system in the governmental hospital. Age of nurses ranged from 28 to 44 years. The experience of ICU nurses ranged between 3 years and 20 years.	68 patients Adult patients (≥18 years) who were mechanically ventilated via endotracheal tube for ≥ 24 hours in multicenter ICUs at Palestinian hospitals. Intervention group (n =34 patients) in the prospective NLWP group. Control group (n = 34 patients) in retrospective UC group. (Table 2.)
Study design	Systematic review with meta-analysis.	A qualitative descriptive research using focus groups.	A quantitative, prospective, quasi- experimental study that compared ventilator weaning protocol led by nurses with matched historical controls (1:1 matching) of retrospective data of UC.

Table 1. Patient characteristics, study design and methods in Studies I-III.

	Study I Systematic review meta-analysis	Study II Focus group	Study III Quasi-experiment
Inclusion and exclusion criteria	We included quantitative studies with a diversity of research methodologies of NLWPs for mechanically ventilated adult patients: (a) RCTs, (b) non-randomized controlled trials, (c) quasi-experimental studies, and (d) prospective and retrospective cohort studies of NLWPs for mechanically ventilated patients. <u>Exclusion criteria:</u> (a) study designs such as case studies, observational studies, qualitative studies, literature reviews, practice development reports, conference reports, practice guidelines, surveys and editorials; (b) weaning protocols implemented by non-nurses; (c) all studies of home ventilation and chronic ventilation settings and non-invasive MV; and (d) studies that exclusively addressed patient populations younger than 18 years of age.	Registered qualified nurses, only those having more than three years professional experience in the ICU.	Patients were included in the study if (1) they received MV via endotracheal tube for \geq 24 hours, (2) they were 18 years or older, and (3) ventilator weaning trial was initiated while patient is in the ICU. <u>Exclusion criteria</u> : If the patients: (1) were on MV for < 24 hours or had chronic ventilation settings, that expected poor long term prognosis, (2) died without extubation or before initiation of ventilator weaning, (3) had tracheostomy at the time of ICU admission, (4) non- invasive MV, and (5) they were less than 18 years of age.
Study period	We searched from the databases CINAHL, PubMed, Scopus and the Cochrane Central Register of Controlled Trials as far back as the database allowed until January 2016.	Two periods: Pre-protocol: The study was conducted in October 2016. Post-protocol: The study was conducted in May 2018.	The study was conducted from February 2017 to March 2018 that compared NLWP of retrospective data of UC- physician-led usual weaning care (between February 2015 to March 2017).

	Study I Systematic review meta-analysis	Study II Focus group	Study III Quasi-experiment
Intervention	The use of weaning protocols led by critical care nurses to wean patients from MV compared to weaning patients from MV without the use of a protocol, that is, physician-led weaning (UC).		The study compared NLWP with matched historical controls (1:1 matching) of retrospective data of physician-led usual weaning care.
outcomes	Outcomes were the duration of MV in days (defined as the period from the day of endotracheal intubation until the day of MV discontinuation); weaning time (time from the identification of weaning readiness criteria to the discontinuation of MV); ICU LOS in days (the period from the day of hospitalization in the ICU until discharge); hospital LOS; hospital mortality; rate of ventilator-associated pneumonia; and rate of re-intubation.		The study outcomes were the duration of MV in days (defined as the period from the day of endotracheal intubation until the day of discontinuation of MV), and weaning time (defined as the time from identification of weaning readiness to successful discontinuation of MV, ICU LOS, hospital LOS, rate of re-intubation, and hospital mortality.

	Study I Systematic review meta-analysis	Study II Focus group	Study III Quasi-experiment
Data collection instruments	The Cochrane Collaboration (2011) guideline.	Focus group interview guide with open- ended questions (Appendix I).	For the intervention group: (a) Study protocol (Appendix II); (b) Chart tool included flow sheet of assessment tool for ventilator weaning readiness, that was designed based on weaning protocol (already included in chart tool of Appendix III). For the control group: UC chart tool was designed, based on routine care of weaning process that was used in clinical practice in Palestinian hospitals (Appendix IV).
Analysis	We performed the meta- analysis using Review Manager 5.3.	Qualitative content analysis applied (Graneheim &Lundman, 2004).	All analyses were conducted using IBM SPSS statistics 21 license. Data was presented as mean and standard deviation (SD), medians and interquartile ranges (IQRs), or proportions, as appropriate. The main assumption of non- parametric test was performed for non-normal distribution of the data.

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3.4- Ethical considerations

Both of Studies (II-III) were approved by the Institutional Review Board (IRB) of An-Najah National University, and permission was obtained from the ethical Committee at the Ministry of Health of Palestine, where the studies were conducted (Appendix VI). Furthermore, the ICU nurses who participated in the studies were informed by the researchers about their rights, the purpose of the study and all related matters of the study research objectives, and study procedures. All participants gave their written consent (Appendix Va, Vb). Results are presented anonymously with full respect for confidentiality of all participants. Participation in the studies was voluntary, and participants had the right to withdraw from study. At the beginning of the study, he researcher repeated the information and asked for consent from the participants. Individuals in the study had the opportunity to pursue and resolve any doubts about the study details. Moreover, we followed the declaration of the ethical principles for medical research involving human subjects, including research on identifiable human material and data. The study followed the World Medical, A. (2013). "World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects." JAMA310 (20): 2191-2194.

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CHAPTER IV - A systematic Review of a Nurse-led Weaning Protocol For Mechanically Ventilated Adult Patients- Metaanalysis

In this systematic review and meta-analysis of nurse-led weaning protocol aims to synthesize the current best evidence for the effectiveness of weaning protocols led by nurses, when compared to usual, physician-led, care. All studies provided a comprehensive description of methods. Pooled data showed significant statistical difference in favor of nurse-led weaning protocol for reducing the duration of mechanical ventilation, Intensive Care Unit (ICU) and hospital length of stay (LOS). This review provides evidence in support of Intensive Care Unit nurses' crucial role and abilities to lead weaning of mechanical ventilation.

An article of this study was accepted to Journal of Nursing in critical care, on October 29, 2018.

Hirzallah FM., Alkaissi A., Barbieri-Figueiredo MC. (2018). A systematic Review of Nurse-led Weaning Protocol For Mechanically Ventilated Adult Patients. Nursing in Critical Care, in press. doi:10.1111/nicc.12404

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ABSTRACT

Objectives: The aim of this systematic review is to synthesize the current best evidence for the effectiveness of weaning protocols led by nurses compared to usual physician-led care.

Background: Protocol-directed weaning has been shown to reduce the duration of mechanical ventilation (MV). Studies have reported that a weaning protocol administered by nurses leads to a reduction in the duration of MV and has a major effect on weaning outcomes. This can have especially positive consequences for critically ill patients.

Study design: Systematic review with meta-analysis.

Search strategy: The databases CINAHL, PubMed, Scopus and the Cochrane Central Register of Controlled Trials were searched from as far back as the database allowed until January 2016.

Inclusion and exclusion criteria: Searches were performed to identify the best available evidence included quantitative studies of nurse-led weaning protocols for mechanically ventilated adult patients. We excluded all studies of weaning protocols implemented by non-nurses and non-invasive MV and studies that addressed patient populations younger than 18 years of age.

Results: The database searches resulted in retrieving 369 articles. Three eligible studies with a total of 532 patients were included in the final review. Pooled data showed a statistically significant difference in favour of the nurse-led weaning protocol for reducing the duration of MV(MD= -1.69 days, 95% confidence interval (CI) = -3.23 to 0.16), intensive care unit length of stay (MD= -2.04 days, 95% CI = -2.57 to -1.52, I2 = 18%, p=0.00001); and hospital length of stay(MD= -2.9 days, 95% CI = -4.24 to -1.56, I2 = 0%, p = 0.00001).

Conclusion: There is evidence that the use of nurse-led weaning protocols for mechanically ventilated adult patients has a positive impact on weaning outcomes and patient safety.

Relevance to clinical practice: This review provides evidence supporting intensive care unit nurses' crucial role and abilities to lead weaning from MV.

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INTRODUCTION

Weaning is the process of discontinuing mechanical ventilation (MV). Intensiv e care unit (ICU) patients spend half of their total ventilator time being weaned (Cederwall et al.,2014). Prolonged MV is associated with higher morbidity, longer hospital stays, and adverse effects for critically ill patients(Blackwood et al., 2011; McConville & Kress, 2012). Various studies suggest that the use of ventilator weaning protocols provides a standardized approach to help patients reduce their stay in the ICU by reducing the duration of MV and improving patient outcomes (Blackwood et al., 2009; McConville &Kress, 2012). Weaning protocols are generally based on three components: readiness to wean criteria, guidelines for reducing ventilator support, and extubation criteria, although the criteria and the content of the guidelines may vary. Furthermore, not all protocols include extubation criteria (Blackwood et al., 2009;2011). Protocols are based on the principle that the collective knowledge of a group (Blackwood et al., 2009) and the common goal of all ICU team members involved in caring for mechanically ventilated patients is successful weaning from ventilatory support (Fulbrook et al., 2004); thus, there is an increased interest in developing weaning protocols that provide structured guidelines and deliver more consistent practice in ICUs(Blackwood et al., 2009). Weaning protocols are guidelines that decrease variability and standardize care in ICUs, which is particularly useful when limited staffing for treatment is available (Plani et al., 2013). Moreover, evidence from previous studies reveals that protocol-directed weaning reduces ventilatorassociated complications, the duration of MV and reintubation rates (Ely et al., 1996; Grap et al., 2003; Kollef et al., 1997; Marelich et al.,2000; McLean et al., 2006). Therefore, the use of protocols allows staff to identify the earliest opportunity for the extubation of any patient capable of breathing spontaneously, optimize extubation timing, avoid both reintubation and overlong intubation, and reduce weaning time (Fulbrook et al., 2004). There is also evidence that the involvement of nurses and therapists in this process is beneficial. Traditionally, weaning patients from the mechanical ventilator and extubation were the responsibility of physicians; thus, they were the major decision makers during weaning. An evidence-based appraisal of the literature suggests that nurses and related health staff might adhere to the protocols more closely than physicians. These findings are supported by a systematic review of randomized controlled trials (RCTs)by Blackwood et al. (2011), which concluded that weaning protocols implemented by non-physician health care staff had a major effect on weaning outcomes and reduced the duration of MV. Nursing involvement in the weaning process has increased over the past two decades with the introduction of weaning protocols (Rose et al., 2011). Critical care nurses play a central role in developing weaning plans with patients (Chrocker, 2009). The decision to wean is based on patient readiness according to compliance with a list of physiological criteria and on the holistic assessment of patients' readiness to wean, to which nurses provide an important contribution(Blackwood, 2000).Weaning is just one example of the complexity of managing ICU patients(White et al., 2011). Research shows that nurses in Australia and New Zealand are frequently independently responsible for the manipulation of ventilator settings titrated to physiologic parameters (Rose et al., 2011).

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Justification for Review

There is a lack of research synthesis exploring the effectiveness and influence of nurse-led weaning protocols on MV outcomes for critically ill adult patients to guide nursing practices. Previous reviews on this subject compared non-physician-driven weaning protocols used by respiratory therapists(RTs)or a combination of nurses and RTs with physician-driven weaning protocols. In this review, we investigated the implementation of weaning protocols led by ICU nurses alone to guide weaning patients from MV. We believe that the current systematic review study is the first synthesis and meta-analysis of nurse-led weaning protocols compared to usual physician-led care.

Objective of Review: The aim of this systematic review is to synthesize the current best evidence for the effectiveness of nurse-led weaning protocols by answering the following question: Do nurse-led weaning protocols reduce the duration of MV, weaning time, ICU and hospital length of stay (LOS), hospital mortality, ventilator-associated pneumonia(VAP) rate, and reintubation rate in critically ill adult patients (\geq 18 years) who have undergone invasive MV compared to usual physician-led care?

METHODS

Inclusion and Exclusion Criteria

Study design: We included quantitative studies with a diversity of research methodologies: (a) RCTs, (b) non-randomized controlled trials,(c)quasi-experimental studies, and (d) prospective and retrospective cohort studies of nurse-led weaning protocols for mechanically ventilated patients.

The exclusion criteria were (a) study designs such as case studies, observational studies, qualitative studies, literature reviews, practice development reports, conference reports, practice guidelines, surveys and editorials; (b) weaning protocols implemented by non-nurses; (c) all studies of home ventilation and chronic ventilation settings and non-invasive MV; and (d)studies that exclusively addressed patient populations younger than 18 years of age.

Patients and Settings

Studies of adult patients (aged \geq 18 years)who were mechanically ventilated and had an endotracheal tube in the ICU were included.

Intervention

The use of weaning protocols led by critical care nurses to wean patients from MV compared to the weaning patients from MV without the use of a protocol, that is, physician-led weaning (usual care).

Outcome Measures

Outcomes were duration of MV in days (defined as the period from the day of endotracheal intubation until the day of MV discontinuation); weaning time(time from

the identification of weaning readiness criteria to the discontinuation of MV); ICU LOS in days (the period from the day of hospitalization in the ICU until discharge); hospital LOS; hospital mortality; rate of ventilator-associated pneumonia; and rate of reintubation.

Search Strategy

We searched PubMed, Scopus, CINAHL, and the Cochrane Central Register of Controlled Trials databases because they are the largest sources of nursing and allied health journals. The databases were searched from as far in the past as they allowed until January 2016. Studies were retrieved with focused searches using combinations of the following terms: mechanical ventilation weaning, mechanical ventilation weaning protocol, mechanical ventilation weaning protocol and critical care nursing. The reference lists of identified articles were examined for potentially relevant citations. No language restrictions were applied. Table 1 presents the records identified through the database search.

Data base	Key wards	Number of articles
CINHAL(n=93)	#Mechanical ventilation weaning # Ventilation weaning AND critical care nursing	597 93
PubMed(n=185)	#Mechanical ventilation weaning. #Mechanical ventilation weaning protocol. # Ventilation weaning nursing protocol.	4714 322 185
Scpous (n= 76)	#Mechanical ventilation weaning protocol. #Mechanical ventilation weaning protocol AND critical care nursing	521 76

Table 1a. Records identified through database search :

Data Extraction

Titles and abstracts of studies were retrieved using the search strategy, screened independently by the first author, and confirmed by the second author to identify studies that potentially met the inclusion criteria outlined above. The full text of potentially eligible studies was retrieved and independently assessed for eligibility by the same two authors. Disagreements between the two authors over the eligibility of particular studies were resolved through discussion with a third reviewer. The two reviewers conducted data extraction and assessed the methodological quality of the studies. The authors pre-developed and piloted a specific data extraction tool that was used to increase the rigor of data extraction according the variables of the study. The extracted information included study identification, study setting, study methodology, participant characteristics, details of the intervention, outcomes and

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results (Table 2).

						,
Study (Author, year, country)	Study design	Sample size (n)	Participants	Interventions	Outcome measures	Results
1-(Danckers	Comparative	202	Mechanically	Control (C)	Duration of	Median
et al 2013)	study with	nationts	ventilated	n = 100	MV in days	duration of
ct al., 2013)	historical	patients	adult	Physician-		MV(d).
USA Now	controls -		nationts for	driven	hospital LOS	$\mathbf{C} \cdot \mathbf{A} \operatorname{days}(2)$
Vork	Δ		more than	ventilator	rate of $V\Delta P$	13) I.
medical	nrospective		24 hours	weaning	hospital	2 days (2-11)
-surgical ICI	Non-		(short term	(historical	mortality	(P = 0.01)
Surgicul ieo	randomized		neriod)	control)	and attitudes	Median
	study		period/		of physicians	length of ICU
	Study			Intervention	toward the	stav (d)
				(l): $n = 102$	nurse driven.	C : 7 days. I : 5
					protocol-	davs. $(P = .01)$.
				Nurse-driven	directed	Time of
				ventilator	ventilator	extubation:2
				weaning	weaning	hours and
				protocol		13minutes
						earlier in the
						intervention
						group (nurse-
						led protocol).
						But there was
						no significant
						difference in
						hospital LOS
						(d):
						C: 18 (6-
						41.5), 1:15
						(1-52), (P=.52),
						mortality
						$(\%) \cdot C \cdot 1 = 0$
						1.15 7
						(P=0.85)
						rate of VAP (%)
						(P = .37) and
						reintubation
						rate(%)(P=1.0)
						between the 2
						groups

Table 2a-	Characteristics	of	included	studies:
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Study (Author, year, country)	Study design	Sample size (n)	Participants	Interventions	Outcome measures	Results
2-(Roh et al., 2012) Korea, medical ICU of the Asian Medical Center (AMC)	Randomized controlled trial (RCT)	122 patients	Patients on mechanical ventilation for more than 12 hours or less than 14 days (short and long term period)	Control (C): n = 61 Physician delivered Protocol Intervention (I): n = 61 Critical care nurse driven ventilator weaning protocol	Weaning time, overall duration of mechanical ventilation, ICU LOS, hospital LOS, and frequency of complications (tracheostomy, failure of discontinuation, death).	Weaning time (hrs): C:47 hours (interquartile range, 24- 168 hours), I: 25 hours (interquartile range, 5.75- 134 hours, (P=0.010). Median(IQR) duration of MV(d): C:6.2 days, I:5.7 days. (P=0.016) Median(IQR) (length of ICU stay (d): C:14 days, I: 12 days, (P = 0.069). Hospital LOS (d): C:41 (27.25- 81.5), I: 39 (22- 64),P=0.576). Hospital mortality(%): C:11(18.0), I: 9 (14.8), (P=0.625). The results also showed the number of patients who successfully discontinued mechanical ventilation was similar in the 2 groups (PBW, 46 patients, 75.4%; UC, 47 patients, 77.0%; P = .832).

Study (Author, year, country)	Study design	Sample size (n)	Participants	Interventions	Outcome measures	Results
3-(Tonnelier	Comparative	208	Patients	Control (C):	The overall	Mean duration
et al., 2005)	study with	patients	were	n = 104	duration of	of MV(d)
France, A	historical		mechanically	conventional	MV and the	C : 22.5 ± 2
university	controls-		ventilated	physician-	ICU LOS,	I:16.6 ± 1,
hospital	A prospective		through an	directed	the overall	(P=0.02)
ICU Centre	cohort study		endotracheal	weaning	incidence of	Mean ICU LOS
(Hospitalier			tube and	(historical	ventilator-	(d)
Universitaire			required MV	control)	associated	C : 27.6 ± 21.7
de			for	Intervention	pneumonia,	I:21.6 ± 14.3,
la Cavale			longer than	(I): n = 104	unsuccessful	(P=0.02).
Blanche)			48 hours.	Nurse-driven	extubation	While ventilator
				ventilator	rates and ICU	associated
				weaning	mortality.	pneumonia,
				protocol		ventilator
						discontinuation
						failure rates
						and ICU
						mortality did
						not change,
						were similar
						between the
						two groups.

Quality Assessment

The methodological appraisal was conducted in accordance with the Cochrane Collaboration's tool for assessing risk of bias (ROB) (Higgins& Green, 2011). The tool ensured the collection of data related to the following six domains: adequate sequence generation, concealment of allocation, blinding, addressing of incomplete outcome data, and elimination of selective reporting and other biases (Table3).

The Cochrane (ROB) tool suggests that it is a step in the right direction. Extensions of the tool for non-parallel group randomized trials and non-randomized studies were identified as a priority (Savović, et al.2014).

Study	Allocation concealment	Blinding (intervention)	Complete outcome data addressed	Free from selective reporting	Free from other bias
1-Danckers et al., 2013	X	\times	\checkmark	\checkmark	\checkmark
2-Roh et al., 2012	\checkmark	X	\checkmark	\checkmark	\checkmark
3-Tonnelier et al., 2003	X	\times	\checkmark	\checkmark	\checkmark

Table 3a: Summary of risk of bias assessment:Cochrane Collaboration Tool forassessing risk of bias

Data Analysis

A narrative synthesis of the findings from the included studies was structured around the type of intervention, target population characteristics, type of outcome and intervention content.

Statistical Analysis

We performed the meta-analysis using Review Manager 5.3 (The Cochrane Collaboration, 2011). Continuous variables, including MV duration, ICU LOS and hospital LOS, were reported as mean differences (MD), medians and interquartile ranges(IQR) with 95% CIs through the application of the inverse variance method. A p value < 0.05 was considered statistically significant. We assessed the heterogeneity of the studies using the I-squared statistic (I2) test, which measures the impact of heterogeneity (I2> 50%, significant heterogeneity). If theI2 index was \leq 50%, the fixedeffects model was selected to calculate the pooled effects; otherwise, a random-effects model was used (Higgins& Green, 2011). In only one of the three studies, the outcome data were available as means and standard deviations (Tonnelier et al., 2005), while in the other two studies, outcomes were reported as medians and interquartile ranges (Danckers et al., 2013;Roh et al., 2012), that we believe they were used the median and interquartile ranges instead of mean(SD), due to the distribution of their data was not in normal distribution, so we approximated the mean and calculated approximate standard deviation estimates from the median and interquartile range according to Hozoet al.(2004) study that revealed that the estimates of the mean were fairly accurate and useful, thus the approximation(s) is in giving a method for estimating the mean and the variance exactly when there is no indication of the underlying distribution of the data.

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RESULTS

The search resulted in369 articles. After the initial screening, 39 articles required further investigation to assess whether they were to be included or excluded from the systematic review. Of the 39 articles retrieved, 30 were excluded. The most common reason for the exclusion of articles was the research design. After the abstract and article review process, we identified 9 articles to retrieve in full text for review. **Figure** 1 illustrates the review selection process with a PRISMA flow diagram (Moher et al., 2009).

Of the 9 articles retrieved, 6 were excluded. The most common cause of exclusion of the articles was weaning protocols implemented by non-nurses(Ely et al., 1996; Kollef et al., 1997; Krishnan et al., 2004; Planiet al, 2013). The study by Rose et al. (2007) was excluded because it was a cohort prospective study(descriptive design), while in the Blackwood & Wilson-Barnett (2007) study, the focus was on nurses' perception, knowledge, and attitudes and not on the patients. **Table 2** provides an overview of the three selected studies, which are described in more detail in the subsequent section.



Figure 1a : Review selection process with a PRISMA flow diagram

Quality Assessment

All the studies had some risk of bias across the Cochrane Collaboration domains (Table3).

The allocation sequence was adequately generated and concealed in only one study (Rohet al., 2012) because it was a prospective RCT. Neither of the other two studies had adequately generated and concealed allocation sequences: one was a prospective non-randomized study(Danckers et al., 2013), and the other was a prospective cohort study (Tonnelier et al., 2005).

Due to the nature of the intervention, the blinding of participants and staff to the intervention was not possible in the three included studies. Thus, in the Roh et al. (2012)study, nurses who were motivated to wean patients were assigned to the nurse-led protocol group; both physicians and nurses were attentive to managing their patients, and they were aware they were being observed. While neither of the two studies (Danckerset al., 2013;Tonnelieret al., 2005) specified whether outcome assessors were blinded to the intervention (they compared prospective intervention groups led by nurses to retrospective data for physician-driven ventilator weaning -i.e., historical controls), the details of outcome assessor blinding were not provided or mentioned in any of the three studies. All the studies reported complete outcome data: the three included studies reported recruitment, attrition, and exclusion adequately for assessment purposes, and all three studies published the weaning protocol and reported all pre-specified outcomes. The three studies' chosen and specified outcomes based on objectives with statistically significant results were reported. The three studies were free of 'other sources of bias', as defined in the Cochrane Collaboration's domain-based evaluation, although sample size calculations were not mentioned in any of the three studies.

Methodological Quality

The three studies clearly described four patient characteristics(gender, age, primary diagnosis, and Acute Physiology and Chronic Health Evaluation II [APACHE II] score). No significant differences were revealed in the baseline characteristics between the intervention and control groups in the three studies, and they were free of selective reporting of results(outcomes). The tools used to measure intervention adherence and outcomes in each of the three studies varied. The weaning methods used in each of three studies also varied (**Table 4**). Two of the studies (Danckerset al., 2013; Rohet al., 2012) secured ethical approval, while Tonnelier et al. (2005) did not indicate whether ethical approval was obtained.

Table 4a: Characteristics of weaning methods for critically ill adults on mechanical ventilation

Study	Screen	Weaning Methods	Extubation criteria
1-Danckers et al., 2013 102 mechanically ventilated patients for more than 24 hours (short term period)	Daily	Spontaneous breathing trial (SBT) for 30 minutes to 2 hourson Pressure Support (PS) = 5-8 cm H2O and continuous positive airway pressure (CPAP) = 0-5 cm H2O One weaning trial per 24 hours	Confirming with an ICU physician
2-Roh et al., 2012 61 patients on mechanical ventilation for 12 hours or less or 14 days or more (short and long term period)	Daily (charge nurses screened mechanically ventilated patients in the medical ICU every morning)	CPAP, SBT and extubations were only allowed from 07:00 to 17:00 Nurses control FIO2, level of positive end-expiratory pressure (PEEP), and inspiratory pressure for 24 hours. For patients ventilated < 72 hrs For patients ventilated >72 hrs: SBT via T-piece, for 30 min was used	Only performed by physicians, monitored the patient for 30 minutes after readiness for extubation
3-Tonnelier et al., 2003 104 patients that required MV for longer than 48 hours.	Daily	SBT for 90 min. using a T-piece, on Oxygen <50%; PEEP <5 cmH2O	Physicians were asked to approve discontinuation of MV following a successful SBT

Three studies were identified that compared a nurse-led ventilation weaning protocol to physician-led weaning by usual care. In these studies, protocols were designed to facilitate weaning and extubation through the use of both screening to assess weaning readiness and a spontaneous breathing trial. Danckers et al. (2013) conducted a prospective, non-randomized study that used a nurse-led protocoldirected approach and compared it with retrospective data for physician-led ventilator weaning (historical controls) to collect outcome data. This was achieved by reviewing the hospital records of all patients with MV admitted to the same medical-surgical ICU during the same period one year earlier (January 2007 to June 2007) to minimize the impact of seasonal variations on indications for MV between the two groups. The aim of the study was to evaluate whether ventilator weaning protocols could improve clinical outcomes. The study was undertaken to examine the relationships of ICU structure, staffing, and acceptability by ICU physicians. The participants were enrolled in the study over a 5-month period. The authors concluded that the results favoured the protocol driven by ICU nurses, which was found to lead to a reduction in MV duration and ICU LOS without adverse effects. A prospective RCT by Roh et al. (2012) compared protocol-based weaning (PBW) with usual care. The aim of this clinical trial of patients on MV was to determine whether a weaning protocol implemented solely by nurses could reduce the weaning time relative to usual care. A total of 122 patients who received invasive ventilation were enrolled in the study for 2 years. The study relied on dedicated MV weaning, which was performed by nurses, for protocol adherence data, and computerized records designed for patients were randomized to the PBW group. The charge nurses screened the mechanically ventilated patients in the medical ICU every morning, and eligible patients were randomly assigned to the PBW or usual care group. Spontaneous breathing trials(SBT) and extubations were only allowed from 07:00 to 17:00. The researchers concluded that the weaning protocol administered by the nurses was safe and reduced the weaning time from MV in patients who were recovering from respiratory failure. Tonnelier et al. (2005) study relied upon a dedicated research nurse to prospectively collect protocol adherence and outcome data for a prospective cohort study using a nurse-led, protocol-directed procedure (cases) and compared them with a 1:1 matched historical control group who underwent conventional physician-directed weaning. Participants were enrolled in the study for approximately one year (from January 2002 to February 2003). The aim of the study was to determine whether the use of a protocol-directed weaning procedure by nurses was associated with a reduction in the duration of MV and ICULOS. Thus, eligible patients were identified for the weaning procedure through daily screening by nurses. Eligible patients required more than 48 hours of MV and had satisfied the eligibility criteria for an SBT for 90 minutes using a T-piece; screening began immediately after ICU admission. The researchers found that nurse-led, protocoldirected weaning was safe and promoted significant outcome benefits.

The three included studies reported on the duration of MV and the length of ICU stay. Two studies reported on hospital LOS and mortality (Danckers et al.,2013;Roh et al., 2012). In contrast, only one study reported on weaning time (Roh et al., 2012), whereas two studies reported on ventilator-associated pneumonia(VAP) rates (Danckers et al., 2013;Tonnelieret al., 2005). Details of the three studies can be reviewed in Table 1 above.

Outcomes

All three studies found a significant decrease in the duration of MV (Danckers et al., 2013; Roh et al., 2012;Tonnelieret al., 2005). While two studies found a significant decrease in the median durations of ICU LOS (Danckerset al., 2013;Tonnelieret al., 2005), one study found a significant decrease in weaning time (Roh et al., 2012), although there was no significant decrease in the ICU LOS. Two of the studies reported no significant decrease in hospital LOS or hospital mortality (Danckers et al., 2013;Rohet al., 2012). Two studies reported no significant decrease in VAP rates (Danckerset al., 2013;Tonnelier et al., 2005).

Duration of MV (days)

Data from three included studies illustrate a statistically significant difference in favour of nurse-led weaning protocols for reducing the duration of MV. The analysis showed a significant difference as the weighted mean results did not go below zero, with the test of overall effect resulting in a p value = 0.03. For data included in the meta-analysis, the chi-squared test for heterogeneity was also significant (p = 0.003), and the I2 test was 83%. The mean number of days by which MV was reduced was 1.69(range from 2 to 6 days) (**Figure2a**).

Figure 2a- Comparison Nurse-led weaning protocol versus Physician-led care. Outcome: Mechanical Ventilation Duration

	Nurse-driven ver	ntilator weaning p	rotocol	Physician-driv	ven ventilator	weaning		Mean Difference	Mean Difference
Study or Subgroup	Mean	\$D	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	IV, Random, 95% Cl
Danckers et al., 2013	2	1.5	102	4	1.83	100	48.3%	-2.00 [-2.46, -1.54]	
Roh et al., 2012	5.7	1.77	61	6.2	3.12	61	43.0%	-0.50 [-1.40, 0.40]	•
Tonnelier et al., 2005	16.6	13	104	22.5	21	104	8.7%	-5.90 [-10.65, -1.15]	-
Total (95% CI)			267			265	100.0%	-1.69 [-3.23, -0.16]	•
Heterogeneity: Tau ² = 1.2 Test for overall effect: Z =	1; Chi² = 11.45, df 2.16 (P = 0.03)	= 2 (P = 0.003); P	= 83%						H H H -100 -50 0 50 Favours Nurse-driven ventilator weaning protocol Favours Physician-driven ventilator weaning

Weaning Time (hours)

One study reported weaning time as an outcome (Roh et al., 2012). In that study, weaning time was defined as the time from enrolment (initiation of weaning) to successful discontinuation of MV. The result was 47 hours (interquartile range, 24-168 hours) in the physician-led group and 25 hours (interquartile range, 5.75-134 hours) in the nurse-led weaning protocol group (p = 0.010). The results represent a significant decrease in the weaning time for patients whose MV was managed using a nurse-led protocol.

ICU LOS(days)

Data from the three studies illustrate a statistically significant difference in favour of nurse-led weaning protocols for reducing the ICU LOS: the weighted mean results were not below zero, and the test of overall effect resulted in a p value = 0.00001. For the data included in the meta-analysis, the chi-squared test for heterogeneity was not significant (p = 0.30), and the I2 test result was 18%. The mean ICU LOS was reduced by 2.04 days (**Figure3a**).

Figure 3a- Comparison Nurse-led weaning protocol versus Physician-led care. Outcome: ICU Length of Stay.

	Nurse-driven venti	Physician-driven ventilator weaning				Mean Difference	Mean Difference			
dy or Subgroup	Mean	\$D	Total	Mean	SD	Total	Weight	IV, Fixed, 95% Cl	IV, Fixed, 95% Cl	
ickers et al., 2013	5	1.83	102	7	2.33	100	81.4%	-2.00 [-2.58, -1.42]		
ı et al., 2012	12	3.75	61	14	3.25	61	17.6%	-2.00 [-3.25, -0.75]	•	
nelier et al., 2005	21.6	14.3	104	27.6	21.7	104	1.1%	-6.00 [-10.99, -1.01]	·	
al (95% CI)			267			265	100.0%	-2.04 [-2.57, -1.52]		
erogeneity: Chi²= 2.4 t for overall effect Z=	4, df = 2 (P = 0.30); I ² 7.68 (P < 0.00001)							-100 -50 0 50 11 Favours Nurse-driven ventilator weaning protocol Favours Physician-driven ventilator weaning	00	

Hospital LOS (days)

Two of the three included studies demonstrated that the nurse-led weaning protocol reduced the length of hospital stay (Danckerset al., 2013;Rohet al., 2012). Figure 4a shows a significant reduction in hospital LOS for the nurse-led weaning protocol group, with p = 0.001. For the data included in the meta-analysis, the chi-squared test for heterogeneity was not significant (p = 0.67), and the I2 test result was 0%. The mean hospital LOS was reduced by 2.9 days(Figure 4).

Substantial heterogeneity of I2 = 83% was found for the MV duration. For the ICU LOS, low heterogeneity of I2 = 18% was found, and no significant heterogeneity was found for hospital LOS.

	Nurse-driven ventilator weaning protocol			Physician-driven ventilator weaning				Mean Difference	Mean Difference				
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% Cl		IV, Fixe	l, 95% Cl		
Danckers et al., 2013	15	4.16	102	18	5.91	100	90.3%	-3.00 [-4.41, -1.59]					
Roh et al., 2012	39	10.5	61	41	13.56	61	9.7%	-2.00 [-6.30, 2.30]		-			
Total (95% CI)			163			161	100.0%	-2.90 [-4.24, -1.56]		•			
Heterogeneity: Chi² = 0.19, df = 1 (P = 0.67); l² = 0% Test for overall effect: Z = 4.24 (P < 0.0001)									-100 -8 Favours Nurse-driven	1 50 ventilator weaning protocol) Favours Physician-driven	1 50 1 ventilator weaning	100

Figure 4a- Comparison Nurse-led weaning protocol versus Physician-led care. Outcome: Hospital Length of Stay.

DISCUSSION

In this systematic review, we assessed evidence from three studies on the effect of nurse-led weaning protocols on the duration of MV weaning time and ICU and hospital LOS in critically ill adults. The results of this review evidenced that the nurse-led weaning protocols reduce the duration of MV, weaning time, and ICU LOS and affect other outcomes for critically ill adult patients compared to usual physician-led care. Meta-analysis showed a significant difference in reducing the duration of MV and ICU and hospital LOS in favour of nurse-led weaning protocols. Only one study (Roh et al., 2012) reported on weaning time and found that it was significantly decreased. Although the data from the pooled summaries alone appear to support nurse-led weaning protocols, they should be viewed with caution because of the significant heterogeneity among studies, particularly in terms of the MV duration (I2= 83%.).

The reduction in the MV duration in our findings is in accordance with earlier RCTs (Ely et al., 1996; Kollef et al. 1997; Marelichet al., 2000) and is also supported by nonrandomized controlled trials (Dries et al., 2004; Plani et al., 2013) and Price's (2001) systematic review of nurse-led weaning from MV. That review found a reduction in ventilation time without additional complications, and the protocol-directed weaning was managed by nurses and RTs. Accordingly, Danckers et al. (2013) and Tonnelier et al. (2005) found that the protocol driven by ICU nurses led to a reduction in the MV duration and ICU LOS without adverse effects. This is similar to the findings of a study by Smyrnios et al. (2002) but contrary to findings of studies (Ely et al., 1996; Grap et al.,2003; Kollef et al., 1997; Roh et al., 2012) that reported no significant decrease in ICU LOS despite a decrease in the duration of MV without explicitly stating the reasons for their results. Another study (Krishnan et al., 2004) did not find a shorter MV duration and ICU LOS; thus, they suggested that their results may be due to the high levels of physician staffing in their closed ICU or to the use of a template on rounds to promote daily discussion of mechanically ventilated patients. Additionally, some physicians, nurses, or RTs changed their practice of usual care for ventilator management because they were aware of the study in progress (Hawthorne effect). Nevertheless, Roh et al. (2012) reported that the nurse-administered weaning protocol established a significant reduction in MV weaning time. This is in accordance with Ely et al.(1996), who found a significant reduction in weaning duration. Our review found a significant reduction in hospital LOS, contrary to earlier studies (Ely et al., 1996; Kollef et al., 1997).Furthermore, we found that the use of nurse-led protocols to guide weaning had no effect on adverse events, including hospital mortality, reintubation, and VAP rate. These findings are in accordance with the findings of Ely et al. (1996), Kollefet al. (1997) and Krishnan et al. (2004). Other studies (Dries et al., 2004; Marelich et al., 2000; Planiet al., 2013) found that ventilator weaning protocols were associated with a decrease in the incidence of VAP.

The weaning protocols that were used in these studies varied. Danckers et al. (2013) and Roh et al. (2012) described PBW that included spontaneous breathing trials with CPAP; for patients who satisfied the eligibility criteria for weaning, the duration of SBTs ranged from 30 to 120 minutes through a ventilator circuit. This is in accordance with 6 other studies (Ely,1996, Kollef et al., 1997; Krishnan et al., 2004; Namen et al., 2001; Marelich et al., 2001; Piotto et al., 2011). However, in Roh et al. (2012),SBT via T-piece was used for 30 minutes for patients who were ventilated for longer than 72 hours. In contrast, Marelich et al. (2000) used weaning protocols consisting of stepwise reductions in synchronized intermittent mechanical ventilation(IMV) and pressure support before the SBT for patients with the same MV duration(>72 hours). In contrast, Tonnelier et al. (2005) used a 90-minute SBT with a T-piece to screen patients who had required more than 48 hours of MV and satisfied the eligibility criteria for readiness for a weaning trial. Indeed, further investigation is warranted to determine whether specific protocols are more beneficial than others for specific populations of patients. The evidence supporting the use of weaning protocols in clinical practice is not consistent across all populations, and the results may indicate that the protocols vary in more than composition alone (Blackwood et al., 2009). Furthermore, this review shows that a nurse-administered weaning protocol is safe and promotes significant outcome benefits for patients on MV. This is in accordance with a study by Rotello et al. (1992) that found that nurses adhere to directed protocols. Additionally, nurses are more readily available than physicians and can successfully wean patients from MV and contribute to better management (Roh et al., 2012). Timely and safe discontinuation of MV is an desirable outcome for patients (Blackwood et al., 2009). Weaning protocols increase nurses' direct involvement in decisions related to patient care and provide an additional avenue for communication with the healthcare team(Rose et al., 2011). Roh et al. (2012) reported that the administration of a weaning protocol by nurses is an effective use of the limited resources in the ICU. The responsibility for identifying patients ready to wean from MV and assisting in the weaning trial can be successfully assumed by ICU nurses (Danckers et al., 2013; Roh et al., 2012; Tonnelier et al., 2005).

Strengths and Limitations of the Review

We believe that our review is the first synthesis and meta-analysis of nurse-led weaning protocols compared with usual physician-led care and that it provides further assurance that ICU nurses alone can guide weaning from MV. In this systematic review and meta-analysis of nurse-led weaning protocols, all studies provided a comprehensive description of methods.

Our challenges were that only three studies of nurse-led weaning protocols were included in this review, and only one study was an RCT. Thus, the results should be interpreted with caution.

A methodological limitation was the inability to blind health staff to the weaning method due to the interventions required for protocol-based weaning; consequently, it is possible that the decisions and actions of health staff could have been influenced, resulting in biased estimates of treatment outcomes. Furthermore, the protocols used in the three studies were different.

Implications for Clinical Practice:

- Nurse-led weaning protocols for mechanically ventilated critically ill adult patients have a positive impact on weaning outcomes.
- Nurse-led weaning protocols for mechanically ventilated critically ill adult patients are safe and viable to implement.
- Health staff should be involved in developing, evaluating and revising weaning protocols as new evidence emerges.

CONCLUSION

The findings show that nurse-driven weaning protocols can be implemented safely and effectively and have a major impact on patients' outcomes. Remarkably, the results emphasize that the weaning protocols led by critical care nurses resulted in reductions in the duration of MV, ICU LOS and hospital LOS and that they are easy to implement, safe, and accepted by the ICU health staff.

Uniform weaning protocols based on the best available evidence minimize variations in clinical weaning practices. Indeed, the protocol is a vital part of the weaning process. Constant re-evaluation and modification of the protocol based on evidence are essential to successful weaning and improving patient outcomes. Critically ill patients need constant care and evidence-based systems of practice. Implications for future research include a need for extensive randomized controlled studies to gain more evidence in support of nurse-led weaning protocols and effective durations of MV, ICU LOS, and hospital LOS.

WHAT IS KNOWN ABOUT THIS TOPIC

- Prolonged mechanical ventilation can be associated with adverse outcomes and higher morbidity in patients
- Ventilator weaning protocols have been reported to reduce the duration of mechanical ventilation, reduce ventilator-associated complications, and have beneficial outcomes for patients.

WHAT THIS PAPER ADDS

- The current study provides additional evidence that nurse-led weaning protocols have a major impact on weaning outcomes compared with usual care.
- Systematic weaning protocols based on evidence can reduce variations in clinical weaning practices and offer an internationally standardized process.
- Standardized weaning protocols led by nurses were effective in reducing MV time and ICU and hospital LOS.

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CHAPTER V - Critical Care Nurses ' Perceptions Towards Nurse-Led Weaning Protocol From Mechanical Ventilation In Intensive care units in Palestine- A qualitative Study"

In this chapter we present the focus group study to identify the perceptions of nurses towards nurse-led weaning protocol from mechanical ventilation in intensive care units, by providing the participants an opportunity for discussing their thoughts and perceptions by interaction between nurses pre and post protocol implementation for mechanically ventilated patients following same interview guide.

An article of this study was submitted, on November, 2017 to Journal of Nursing & Health Sciences (NHS).

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ABSTRACT

Aim: The aim of this study is to identify nurses' perceptions toward nurse-led weaning protocols; pre – protocol, and post – directed weaning protocol, for mechanically ventilated adult patients in Intensive Care Units (ICU) among Palestinian hospitals.

Methods: A qualitative descriptive research design, with focus groups in two occasions, was used following the same interview guide. Focus groups were conducted in the ICU's of two governmental Palestinian hospitals, one in each hospital; pre-protocol, and post-protocol. Each group had between 11 and 13 participants. The interviews were recorded and transcribed verbatim.

Results: The content was thematically categorized. Six themes emerged: (i) Agreement/Support: (ii) Increased Awareness; (iii) Nursing expertise and qualifications for leading weaning protocols; (iv) Improved Patient Outcomes; (v) Inter-Professional Collaboration; and (vi) Barriers to nurse-led weaning. The findings demonstrate a positive impression and acting toward nurse- led weaning protocol from health professionals among Palestinian hospitals.

Conclusion: A common weaning plan provides a standardized weaning process that positively reduced weaning trials and delays, and improved patient outcomes.

Keywords: Critical Care Nursing, Clinical Protocols, Middle East, Respiration, Artificial, Ventilator Weaning.

INTRODUCTION

Intensive care patients spend 40-50% of the total ventilator time on weaning(Cederwall et al., 2014). The basic goal for using ventilator-weaning protocols is to provide a standardized approach to improve patient outcomes in this critical area (Blackwood et al., 2009). Ventilator Weaning Protocols have been developed to reduce undesirable variations in the process of weaning (Hansen & Severinsson, 2007). Weaning protocols offer an internationally standardized process of practice that can be applied locally to improve outcomes (Blackwood & Wilson-Barnett, 2007). Critically ill patients need constant care and evidence-based systems of practise (Haugdahl et al., 2014). Critical care nurses playing a central role in developing weaning plans with their patients (Crocker & Scholes, 2009). Evidence-based appraisal of the literature suggests that nurses and related health professionals may even adhere to protocols more closely than physicians (Blackwood et al., 2011). A study by Blackwood et al (2007) demonstrated that nurse-directed weaning (protocol based) had positive effects of increasing the patient's perceived level of knowledge of the care nurses, increased awareness of weaning plans, and demonstrated patient satisfaction with communication toward using the weaning protocol. Consequently, recent studies have compared weaning protocols led by nurses with physician directed weaning. Results indicate that nurseled weaning protocols have a major positive impact on patient outcomes (Danckers et al., 2013; Roh et al., 2012; Tonnelier et al., 2005). Mechanical ventilation weaning requires expert knowledge and skill (Crocker, 2002). The relevance of nurse involvement in ventilator decision making is reliant on the nurses' knowledge and skills in managing ventilation (Rose et al., 2011). A critical aspect of the process is sharing and comparing experiences of the weaning protocol in a group. The difference of perceptions between physicians and nurses toward the role of the ICU nurse, may have an impact on practice in the area of ventilation weaning (Haugdahl et al., 2014). The aim of this study is to identify the perceptions of nurses and physicians' toward nurse-led weaning protocols in Intensive Care Units (ICU) in Palestinian hospitals. This study is the first investigation of this topic in Palestine. Previous studies exploring the perception of protocol-directed weaning in Intensive Care Units were completed in Norway and the UK (Hansen & Severinsson, 2007). One study investigated Intensive Care Unit nurses' and physician's perceptions of protocol-directed weaning in Norway (Hansen et al., 2009). A qualitative study in the UK by Blackwood et al. (2004) explored Intensive Care Unit physicians' views on weaning from mechanical ventilation and the coordinate role of nurses in the weaning process.

In the current study, the impact of the perceptions of both nurses and physicians on weaning were investigated in Palestine, a never before studied phenomenon.

LITERATURE REVIEW

Many studies have shown that ventilator-weaning protocols have reduced weaning times in patients when compared to usual care (Rohet al., 2012). Protocol led weaning has been found to be effective specifically in reducing the duration of mechanical ventilation for patients(Blackwood et al., 2009; Crocker, 2002).

Weaning efforts may be affected by a variety of factors including limited physician availability at the bedside (Blackwood et al., 2009). ICU nurses maintain a near continuous presence at the bedside, hence may be better positioned to titrate ventilator settings in response to changes in physiologic parameters (Rose et al., 2011). Nurses are responsible for fewer patients than physicians, and may be able to respond more rapidly to changing patient status by making suitable adjustment to respiratory parameter, allowing for a higher quality and rapid weaning (Roh et al., 2012). Nurses may have a greater understanding of the patient because they have increased ability to observe while working closely with the patient (Eckerblad et al., 2009). Crocker & Scholes, (2009) found that expert nurses were experienced in weaning and had sufficient knowledge about the patient to inform their actions. Nursing, like other applied medical disciplines, is complex; the clinician must make critical decisions in response to changes in the patient's status and the nature of their clinical condition over time (Benner, Tanner & Chesla, 2009). Patients in Critical Care Units represent some of the most complex cases and complicated medical situations (Galvin, 2010). Weaning is just one example of the complexity of managing ICU patients(White et al., 2011). Protocolized weaning is a detailed intervention as defined by Blackwood et al. (2009). Weaning is technically complex, and necessitates knowledge of the respiratory, system, physiology, pathophysiology, pharmacology and current technology (Tingsvik et al., 2015). The intensive care nurse is in a unique position for adopting holistic approaches to weaning. Such procedures require teamwork and consideration of all the factors that could influence the outcome of the weaning process (Mårtensson & Fridlund, 2002). Research shows that nurses in Australia and New Zealand were frequently independently responsible for the manipulation of ventilator settings titrated to physiologic parameters (Rose et al., 2011). Roh et al. (2012) demonstrated that a physician's order was required only for extubation when a patient met objective extubation criteria. The effectiveness of protocolized-weaning is influenced greatly by existing intensive care unit working practices (Blackwood et al., 2007). Weaning patients early and successfully from mechanical ventilation relies on a team approach (Chroker, 2002). Nurse-directed protocolized-weaning must be evaluated by measuring its impact on patient outcomes (Blackwood et al., 2007). Safe and timely discontinuation of mechanical ventilation is a desirable outcome for patients and clinicians (Blackwood et al., 2009). Weaning protocols have increased the direct involvement of nurses in decisions related to patient care and has provided an additional avenue for communication for the healthcare team (Rose et al., 2011). The use of a nurse-directed weaning protocol may increase the nurses' knowledge and

sense of autonomy, both through training in and continued use of the protocol, the nurses may gain comprehensive and valuable knowledge of respiratory assessment and mechanics that allows them to actively contribute to improved outcomes for patients (Blackwood et al., 2007;Grapet al., 2003).According to Crocker, (2002) a delay in initiating the decision to wean may be due to lack of knowledge, lack of support or failure of the guidelines.

Study aim

The aim of this study is to identify nurses' perceptions toward nurse-led weaning protocols; pre – protocol, and post – directed weaning protocol, for mechanically ventilated adult patients in Intensive Care Units (ICU) among Palestinian hospitals, by means of focus group interviews and qualitative content analysis.

METHODS

Design

A qualitative descriptive research design using focus group.

The ICU nurses were interviewed in two focus-groups that conducted in the ICU's of two governmental Palestinian hospitals,once in each hospital; pre- and post-protocol focus group, using same interview questions guide (Appendix I). Each interview was audio-recorded and lasted for 40-50 minutes in duration. Focus groups were held in rooms close to the ICU, for staff convenience. One room was utilized as a "meeting point", where health care workers could listen to each other's questions and utilize each other's expert knowledge. As a way of facilitating the participation, the focus group was completed during regular working hours. The interviewswere recorded, and transcribed verbatim to reduce bias and improve the credibility of the analytical process.

Recruitment and sample

Nurses are recruited by the nurse managers from variable shifts for voluntary participants, including: RN Qualified; only those having more than three years professional experience in ICU.

Participants

The participants were13 nurses were interviewed at both hospitals; pre- protocol focus group:(six nurses in the first group (Ramallah nurses), and seven nurses in the second group (Rafidia nurses), and 11 nurses were interviewed post protocol: (five nurses in the first group (Ramallah nurses), and six nurses in the second group (Rafidia nurses). The other two were unavailable, because of the rotation system in the governmental hospitals.Nursing staff were interviewed in a group setting. The participant age ranged from 28 to 44 years. Their experience of intensive care nursing ranged from 3 years to 20 years.

Reasons for choosing the focus group method

Focus group method is the process of sharing and comparing self-reported behaviour and experiences to find out what the participants think about an issue, and why they think the way they do, is one of the most valuable aspects of focus groups. Group discussions provide direct evidence about similarities and differences in the participants' ideas and exploration of experiences(Morgan, 1997; Kreuger, 2008). Focus groups provide less depth and detail about the opinions and experiences of the participants, rather than to learn more about each informant in detail, as the individual interview, thus, the depth and detail were considered of less importance than the process of sharing and comparing experiences of the weaning protocol in a group.

In this study, the aim of using focus group method to provide the participants with an opportunity for discussing their perceptions of Nurse lead weaning protocol and allow the researcher to observe group interaction. The purpose of the pre-protocol focus groups was to identify nurses' perceptions toward nurse-led weaning protocols. And post protocol to identify nurses 'experience and challenges of protocol-directed weaning that lead by nurses.

Participants were chosen in order to reflect general perceptions of involved nursing professionals with experience using the protocols. Qualitative Content Analysis (Graneheim&Lundman, 2004) was used to breakdown the interview texts. The content and classification of themes were discussed and validated by the authors to ensure cohesion.

ETHICAL CONSIDERATIONS

The study was approved by the Institutional Review Board (IRB) of An-Najah National University, and the ethical committee at the Ministry of Health of Palestine. The participants were informed about the purpose and method of the study and insured that they were free to withdraw at any time. Confidentiality was guaranteed at each step of data collection, storage and analysis. Individuals were invited by their nurse manager to participate. Those who agreed were asked for permission to audio-tape the interview/ focus group. In addition, all names were removed from transcripts, so that no subject could be identified. After the categorization of the text and the completion of the final report, all audio tapes and documents from each interview was destroyed.

QUALITATIVE CONTENT ANALYSIS

A qualitative content analysis in several steps was applied to the current data set (Graneheim& Lundman, 2004). The common patterns relating to the participants' beliefs; similarities and differences in their opinions and experiences related to nurse led weaning protocols, were identified and categorized looking for generalized themes.

The internal validity of the study focuses on methods to ensure that the researcher has conducted the research process by exactly representing the participants' ideas (Vaismoradi, Turunen, &Bondas, 2013). The first author, acted as an internal moderator to facilitate group processes and interactions, encouraged group members to equal participation and redefined the interview as needed. The audio tapes were transcribed by the first author. All interviews were recorded and transcribed in an orderly, unbiased fashion. In order to ensure validity, the researchers used facilitators as supervisors of the focus groups (Cosser, 2005). Authors discussed and interpreted material and reflections with facilitators in order to confirm the reliability of the results. Participants were informed via the consent form that they would receive written feedback on the research report. The context in which qualitative data collection takes place contributes to the interpretation of data and as such the generalization of qualitative research is limited.

FINDINGS

Interview data revealed positive perceptions related to nurse led weaning protocol in ICU's among Palestinian hospitals. From the focus group interviews, five themes emerged:

Agreement/ Support of Nurse-Led Weaning Protocols

The participants expressed the perception that nurse led weaning protocol are positive and needed in the current context.

Pre protocol

Nurses expressed the theme as follows

"I firmly believe that we need to have weaning protocol and that a nurse should lead it" (Group1, Nurse2).

"We have been waiting a long time to have a protocol for weaning in ICU" (Group 2, Nurse1).

Post protocol

The participants expressed the perception that nurse are able take decision to lead weaning protocol with positive outcomes

"Right now we have a protocol and based on evidence based practice (EBP), thus the physician no longer against us, and become agree with us in our decision of weaning" (Group2, Nurse2).

"Now we have a criteria to follow it in the weaning patient, and we only call the doctor for extubation" (Group1, Nurse 4).

"Most of the weaning decisions become taken by us for not risky patient, and the physician agree with us" (Group1, Nurse5).

A awareness of Nurse-Led Weaning Protocol

Nurses reported that using weaning protocol raised awareness in weaning processes amongst ICU nurses, including earlier identification of weaning readiness criteria, improved documentation skills and clinical judgment that led to increased professional competency and autonomy.

Pre protocol

"When become oriented in weaning protocols we are able to decide if the patient is ready to wean or not" (Group2, Nurse1).

"I think the ventilator weaning protocol will help nurses to identify patient readiness to wean" (Group1, Nurse1).

Post protocol:

"Right now, we have very good background of weaning process, and we are able to decide if the patient can be wean or not, or if the patient achieved weaning criteria to start weaning" (Group1, Nurse2).

"Knowledge of nursing has been improved, they were become able to determine whether the patient could be wean or not, based on criteria of weaning protocol)" (Group2, head Nurse).

"Weaning protocol improved the nurses documentation, thus their note become systematic and based on evidence and scientific based." (Group1, head Nurse).

"I was relying on the physician or the nursing manager in weaning patient, but now after the existence of a protocol, I become more confidence in weaning process"(Group1, Nurse4)..

"Right now we have protocol, and become more confidence to wean the patient, based on protocol criteria""(Group1, Nurse6)...

"Now we become able to assess the patient and decide if the patient can be wean or not, because we have a protocol, and the physician agree with us (Group2, Nurse2)".

Nursing expertise and qualifications for leading weaning protocol

ICU nurses expressed their support of nurse led protocol, stating that experienced nurses are qualified and capable of managing weaning per specified and standardized procedures. However, some barriers to implementation were noted and addressed, including the difficulty in maintain the required nurse-patient ratio (1:2) for the protocols in Palestinian hospitals, which frequently experience staff limitations.

Pre protocol

"We are able to lead the weaning protocol but the capability is based on nursing

experience, If the nurse has good experience in ICU, she will be able to lead weaning protocol " (Group 2, Nurse 4).

The ICU nurses added that, they are expertise in the weaning process, as well as in titrating ventilation parameters as advanced nurses.

Post protocol

We become discuss the physicians based on evidence based practice, we have benefited from this process of weaning protocol" (Group2, Nurse1)

Despite positive attitudes towards nurse led weaning, the findings revealed certain barriers as well related to nurse lead protocols such as the difficulty in maintaining the required nurse patient ratio (1:2) in local hospitals, related to work overload, that will make difficult for the nurse to be responsible for leading a partial or full weaning process.

"Depending on the staff limits, nurse-patient ratios are supposed to be (1: 1) or max. (1: 2) but in our ICU, the nurse-patient ratio is sometimes (1: 3) or (1: 4);so according to staffing we decide if we can implement protocols or not.

Improved Patient Outcomes

Nurses stated a believe that one important result of using weaning protocol in ICU is that improved patient outcomes by providing a standardized weaning process which was reduced weaning trials, weaning delays, and shorten weaning time, as well as strengthening continuity of care.

Pre protocol:

Nurses expressed the theme as follows

"When the protocol is available, it will reduce the time of patients on MV, it will definitely reduce the weaning time" (Group2, Nurse1).

"We use the weaning criteria already reflected, but it is not written, although it is known to everyone in the health team in general, we use this until you develop a systemization process, a written protocol for weaning" (Group1, Nurse1).

Nurses expressed that they need weaning protocol in Palestinian ICU's, that could be use in the absence of a physician or when the physician are busy with other patients, instead of waiting for a physician's order and delaying the weaning process.

"Presence of weaning protocols are needed that will help us to start weaning, while the physician is very busy with his patients, instead of delaying the weaning"(Group 2, Nurse 6).

"In some cases, the anesthetist comes and puts the patient on deep sedation because

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he doesn not want to awaken the patient and delay weaning, when he is busy in the operating room" (Group2, Nurse7).

"Sometimes the physician tells us to stop weaning, because they are very busy"(Group2, Nurse 6).

Post protocol

" Prior to the existence of the Protocol patient was waiting for two to three days on MV, until the decision is taken by the doctors, now our decision based on weaning criteria start earlier, and the patient staying on MV become less than before (short period)"

"We were waiting for the doctor until he came and write the order if the patient could be weaning or not, now we have a criteria to follow it based on protocol and we can start weaning"(Group2, Nurse2).

Inter-Professional Collaboration and Patient safety

Nurses suggested that using a common weaning plan may enhance inter-professional collaboration as sharing responsibility increased between members of the health care team, which should led to improved patient safety.

Pre protocol:

Nurses expressed the theme as follows

"We need a protocol where physicians and nurses share in a common weaning plan" (Group2, Nurse 6)

"We have the ability to lead the weaning protocol but with constant communication with the doctor" (Group 2, Nurse 5).

Nurses assured that patient safety is based on the experience and knowledge of the nurses who will lead the protocols.

"Patient safety, depends not just on the educational knowledge of the nurse, but also depend on their experience based knowledge "(Group1, Nurse 4)

"It is safe to let ICU nursing to perform a weaning protocol, but only if the nurse has experience of the ICU"(Group 2, Nurse 3).

Post protocol:

"Just qualified nurse who could led weaning protocol and achieved safety for the patients""(Group1, Nurse1).

-"We believe the safety of the patient with nursing following evidence based protocol is higher than physician""(Group 2, Nurse 3).

"weaning successful for patient who weaned based on criteria and nursing recommendation better than the physician because he doesn't know about the patient in detail -like us (as a nurse who spend 8 hours with patient) - he comes by the sudden and weaning readiness criteria for patient still not achieved". "(Group 2, Nurse4).

Barriers to nurse-led weaning

The findings highlighted certain barriers that are present in the current absence of weaning protocol. In some cases there is no regular communication between physicians and nurses that led to a slow weaning process.

Pre protocol:

Nurses stated that some physicians make weaning and extubation decisions without informing the nurses in ICU, as evidenced in the following statements:

"Sometimes the physician comes and makes changes on ventilator parameters without informing any nurse " (Group 1 , Nurse4).

Participants also mentioned that sometimes physicians did not see the patients until nursing staff ask the physician to come.

" Usually, physicians knew nothing about the patient unless the nurse asks them to come to see the patient or approve weaning and extubation because they are in charge of so many patients " (Group2, Nurse1)

Post protocol

Nurses mentioned still some physicians against nurse lead weaning process

"Sometimes the physician comes and determines the need for extubation while there are still certain criteria for weaning that are not met or do not exist for extubation of the patient"(Group 2, Nurse4)

Without a protocol there is no continuity, weaning sometimes happens by chance (Group 2, Nurse 2).

DISCUSSION

The overall results of the current investigation demonstrated supporte of the ICU nurses related to nurse-led weaning protocols in Palestinian ICU's. Themes reiterated that such protocol led to improved patient outcomes, the prioritization of patientsafety, enhancement of inter-professional communication, as well as an increased in professional competency. According to Hansen et al. (2008), who studied in a Norwegian ICU how physicians perceived protocol-directed weaning by nurses, results demonstrated that the physicians accepted the protocol, and felt it had a positive influence on weaning, and enhanced efficiency. A related study found that ICU nurses percieved the protocol as useful, and allowed the nurses to act in the physicians

of a physician (Hansen and Severinsson, 2007). Weaning decisions are often nursing care in nature. Nursing staff stressed that ICU trained/experienced nurses should have ability to lead weaning protocols and that they are experts in the weaning process and titrating ventilation parameters.

Current findings are consistent withqualitative exploratory study findings in the UK by Blackwood et al. (2004) that control role with experience, and education depending on the experience of the nurse. They found that physicians noted experienced nurses often undertook these triple roles, and could recognize differences in objective parameters, but less experienced nurses could not. ICU nurses maintain a close continuous presence at the bedside and therefore may be best positioned to titrate ventilator settings in response to changes in physiologic parameters (Rose et al., 2011). According to the study by Roh et al. (2012), nurses, were able to respond more rapidly to changing patient status by making suitable adjustment to respiratory parameters, and allowing more rapid weaningbecause they are responsible for fewer patients than physicians. A similar observation was reported by Haugdahl et al. (2014) demonstrating that nurses have greater autonomy regarding decisions on mechanical ventilation, including increased influence and collaborative interaction than physicians, as perceived by nurse managers. Thus the nurse can detect early signs of exhaustion or anxiety of the patient and read the cues of discomfort before physiological changes are noted (Chroker, 2002). Furthermore, Blackwood (2000) emphasize that the assessment of readiness for weaning that can only be recognized by bedside nurses, and acknowledge the important role of the nurse in the weaning process.

Knowing the patient, per direct patient care, leads to expertise and improved continuity of care (Crocker& Scholes, 2009). Increasing acknowledgment and awareness of the ability and role of cursing staff may promote inter-professional collaboration and ultimately improve patient care(Haugdahl et al.,2014).

According to Roh et al (2012) the implementation of nurse-directed weaning protocol may contribute to overall better management of ICU patients.Weaning protocols provide a uniform method of practice in the area of weaning (Blackwood et al., 2007). The findings of the current study are in accordance with Hansen et al (2008) who reported that physicians noted that weaning protocols that occurred in their absence led to an increased interest in weaning among the ICU nurses, reduced weaning delays as well as ensuring a standardized weaning process.In the current investigation nurses referred to the positive benefits they gain from having a structured guide. The use of a nurse-directed weaning protocol may increase the nurses' knowledge and sense of autonomy. Through education and use of the protocol, nurses gain comprehensive and valuable knowledge of respiratory assessment and mechanics which allows them to actively contribute topositive outcomes for patients (Blackwood et al., 2007; Blackwood et al., 2004; Grap et al., 2003). Heath, (2009) found weaning patients from ventilators requires education and clinical experience in holistic nursing

environments. Hansen and Severinsson (2007) stated that using a protocol makes it easier to continue the weaning process with patients, as it provides a specific procedure and facilitates understanding of the process.

The participants in this investigation, underlined the importance of effective communication and collaboration between physicians and nurses. Nurses reported that at times they are waiting for a physicians order that delays or slows the weaning process. Nurses related that currently most of time they are sharing in responsibility and decision making in weaning patients with physicians, therefore a common weaning plan should lead to improved professional interaction and prioritization of patient safety. Hence, patient safety depends on the knowledge and expertise of the nurses as well asall members of the health team. These findingsare in concordance with Hansen and Severinsson (2007), who emphasize that in order to improve patient safety, healthcare providers must support team learning through frequent sharing of insights and concerns throughout organizational systems. Protocols are intended to reduce practice variation and improve efficiency in providing care (Blackwood et al., 2009). According to Rose et al., (2011)protocolsincrease nurses direct involvement in decisions related to patient care and have provided an additional avenue for communication within the healthcare team. A study by Roh et al. (2012) hasrecentlyshown that weaning protocols administered by nurses for mechanically ventilated patient were safe and easyto implement. Each professional in the team has special expertise that can lead to improvepatient management (Hansen & Severinsson, 2007). Nurses reported that one of the barriers for using the protocols will bechallenges in ensuring a staff: patient ratio of 1:2 in local hospitals with limited professional staff. Tobin, (2004) reported that weaning forms an enormous workload for intensive care staff. Hansen et al. (2008) revealed a significant gap between time available for weaning and time actually used for weaning in nurse ledprotocols. This means that the decision to implement weaning protocols lead by nurses if not based on actual staffing patterns may deliver negative consequences. Rose et al. (2011) found that the nurse-patient ratio and the presence of a protocol affected collaborative decision making for ventilation weaning. Effective collaboration among nurses and physicians, open communication and shared team goals are known to improve he quality of carefor patients (Haugdahl et al., 2014). According to Roh et al (2012) the implementation of nurse-directed weaning protocol may contribute to overall better management of ICU patients. Weaning protocols provide a uniform method of practice in the area of weaning (Blackwood et al., 2007).

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Study Limitations

There were limitations in current study. One limitation was small participant numbers of groups due to the workload and a shortage of nurse in the unit. Another challenge was that some of nursing staff in one of the hospital had short experience in ICU,

so the nurse manager couldn't recruited for study, as a rotation system between wards related to the policy of the hospital. Another limitation for focus group methods that can be criticized for the dominance of some voices over others, with potential distortion of the views of the group. The facilitator attempted to overcome this by encouraging participation from all of the group members, and checking out responses from more vocal participants.

CONCLUSION

The main findingsof this study were that ICU nurses hold a positive overall impression and supported nurse-led ventilator-weaning protocols after directed in intensive care units and find it viable for applicability among other ICU's among Palestinian hospitals. Nurses emphasised that a protocol was essential for standardizing the weaning process that improved patient outcomes. Participants stressed that they were in need of weaning protocols in their ICUs and that they were strong recommend that such protocol be used in the absence of a physician. By increasing the sharing of knowledge and experience between ICU team members it was suggested that interpersonal collaboration was enhanced and patient safety optimized after the ICU nurses directed weaning protocol. In addition, they reported that increasing nursing skills, roles and judgement in clinical practice based on evidence based parctice(EBP) led to a better multidisciplinary health team cooperation. For further research it is necessary to focus on inter-professional collaboration and to interview other ICU team group, like physicians.

Implications for clinical practice:

-A common weaning plan can provide a standardized weaning process that may positively reduce weaning trials and delays, and there for improve patient outcomes.

-Nurse-led weaning protocols are perceived by health staff as likely to have positive effects on collaborative decision making for medical teams related to ventilation weaning.

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CHAPTER VI - The Impact of Nurses-led Weaning Protocol on Outcomes of Mechanically Ventilated Critically III Patients Among Palestinian Hospitals

In this chapter, we adopted to conduct quantitative study design; a prospective, quasi-experimental study since it was intended to determine the effectiveness of weaning protocol implemented by exclusively by critical care nurse on outcomes of critically ill patients, for a period of approximately 13 months. We highlight the need to develop; nurses role using a weaning protocol intervention, and increase awareness of weaning protocol among ICU nurses, and how the weaning protocol will contributes to decrease duration of MV, weaning time, decreasing the number of reintubation rate.

An article of this study is currently under progress to be submitted to Journal Of Critical Care.

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Abstract

Objective : The main objective of this experimental study -quasi is to determine if the weaning protocol led exclusively by critical care nurse reducing the duration of mechanical ventilation(MV), weaning time, intensive care unit (ICU) and hospital length of stay (LOS), and Reintubation rate, and hospital mortality in critically ill adult patients who received invasive ventilation at the time of study enrolment compared to usual care(UC) of weaning among intensive care units of Palestinian hospitals.

Methods: A quantitative, prospective, quasi-experimental study design, was conducted from February 2017 to March 2018 that compared nurse -led weaning protocol (NLWP) with a matched historical controls (1:1 matching) of retrospective data of usual care(UC); physician-led usual weaning care (between February 2015 to March 2017). A total of 68 adult patients (\geq 18 years) who were mechanically ventilated via endotracheal tube for \geq 24 hours, in multicenter ICU's at Palestinian hospitals. NLWP for the intervention group (n =34), and UC of weaning in the control group (n = 34). The protocol was presented to the ICU health staff during a training session.

Results: There were no significant differences in the 2 groups at baseline. Median durations of mechanical ventilation (MV) in the NLWP and UC groups were 24 hours,(IQR=30hrs), (min-max =24-110) and 48hrs (IQR=48hrs), (min-max =24-216), respectively (P = .034). Median of weaning time in the NLWP and UC groups were 2 hours(IQR=2hrs), (min-max = 1-4) and 4 hours(IQR=3hrs), (min-max =2-13), respectively (P = .001). Median durations of ICU length of stay (LOS) in the NLWP and UC groups were 5 days(IQR=5 days) (min-max = 2-17) and 7 days(IQR=6 days), (min-max =2-26), respectively (P = .03). There was statistical significant differences in Reintubation rate (%) in the NLWP and UC groups was 3/34 (8.8%) and 11/34 (32.4%), respectively (P=0.016). There was no difference in hospital LOS, and hospital mortality between the 2 groups.

Conclusion: Our results clearly indicate that nurses-led weaning protocol was associated with shorter in duration of MV, shorter weaning time, shorter ICU LOS and less of Reintubation rate. Implementation of nurse-led weaning protocols(NLWP) can help better outcomes of ICU patients in Palestine.

Implications for clinical practice: This study provides further evidence about nurses important role in intensive care units, and nursing autonomy in decision making for improved outcomes of mechanically ventilated critically ill adult patients.

Key words: Critically ill, Mechanical ventilator, Nurses, Weaning protocol

Introduction

Approximately 50% of intensive care unit patients need mechanical ventilation (MV) (Metnitz et al., 2009), these patients spend half of the total ventilator time on weaning(Cederwall et al., 2014). Prolonged MV is associated with many adverse physiological and psychological experiences and serious complications resulted in increase in hospital length of stay (LOS), morbidity and mortality (Plani et al., 2013). Protocol led weaning has been found effective specifically in reducing the duration of mechanical ventilation and weaning time for ICU patients rather than usual care (Blackwood et al., 2011; Blackwood et al., 2009; Crocker, 2002; Roh et al., 2012). Blackwood et al.(2010) revealed in his study that both the ventilator time and the ICU stay are reduced if the weaning takes place in a structured approach by means of a protocol. Protocols are based on the principle that the collective knowledge of a group (Blackwood et al., 2009). The common goal of all ICU team members involved in caring for mechanically ventilated patients is successful weaning from ventilatory support (Fulbrook et al., 2004); thus, there is an increased interest in developing weaning protocols that provide structured guidelines and deliver more consistent practice in ICUs (Blackwood et al., 2009). Evidence-based appraisal of the literature of randomized controlled trials and non-randomized controlled supported that nurses and related health professionals adhere to protocols more closely than physicians, and had a major effect on weaning outcomes, and reduced the duration of mechanical ventilation (Blackwood et al., 2011; Dries et al., 2004; Plani et al., 2013). Consequently, recent systematic review of previous studies (Hirzallah et al., 2018, in press) have been evidenced that the nurse-led weaning protocols reduce the duration of mechanical ventilation, weaning time, ICU length of stay (LOS) compared to physician-led usual care(UC), and that they are easy to implement, safe, and accepted by the ICU health staff. And concluded that the use of nurse-led weaning protocols from mechanically ventilated adult patients has a positive impact on weaning outcomes and patient safety. Thus timely and safe discontinuation of MV is an desirable outcome for patients (Blackwood et al., 2009). This is confirmed that nurses can successfully wean patients from mechanical ventilation using well-defined protocols and accelerate the weaning process.

The purpose of this study was to assess whether the protocol led by ICU nurses decreases duration of MV, weaning time, and ICU and hospital length of stay (LOS), and re-intubation rate and hospital mortality in critically ill adult patients compared with physician-led usual care of weaning among Palestinian hospitals. Qualitative study to elict perceptions of nurses towards this innovation was conducted concurrently with this quantitive study. We believe that our study is unique because it is the first study of this kind conducted in Palestine and that provides further evidence of nurses-led weaning protocol that can contribute to better outcomes of ICU patients.

Materials and methods

1.1. Study design

A quantitative, prospective, quasi-experimental study design, was conducted from February 2017 to March 2018 that compared ventilator weaning protocol- led by nurses with a matched historical controls of retrospective data of usual care. We employ a matched control group (1: 1 match) in patients identified from a historical database to ensure equality between two groups. Our Sample consisted of 68 adult patients (\geq 18 years) who were mechanically ventilated via endotracheal tube for \geq 24 hours at the time of study enrolment in multicentre ICU's, in Palestinian hospitals.

For historical control, we reviewed hospital charts by health information system (HIS) at the hospitals for all patients with MV admitted to the same medical and surgical ICU's during the same period from (February 2015 to March 2017) and weaned from MV by usual care weaning. The same period was chosen to minimize impact of seasonal variations on indications for MV between the two groups. The list of potential controls was reviewed for the best possible match controls were selected based on matching in inclusion criteria.

1.2. Patient selection/sample

The study population consisted of 68 patients admitted to the multicenter ICU's at Palestinians hospitals in Nablus, and Ramallah cities / west bank, during the study period. Patients were included in the studies if (1) they received MV via endotracheal tube for \geq 24hours, (2) they were 18 years or older, and (3) ventilator weaning trial was initiated while patient in ICU.

Patients were excluded from the study if (1) they were on MV for < 24 hrs or no possessive pronouns in research had chronic ventilation settings, that expected poor long -term prognosis (2)they died without extubation or before initiation of ventilator weaning, (3) they had tracheostomy at the time of ICU admission, 4)non-invasive mechanical ventilation, and (5) they were less than 18 years of age.

1.3. Intensive care unit structure and design

The study was conducted in Palestinian governmental hospitals, West bank, in Medical /Surgical ICU at Palestine medical complex (PMC) hospital and Surgical ICU at Rafedia hospital. Both ICU's have a 10 beds each (adult and pediatric beds), thus adult beds at ICU in Rafedia hospital included (7 adult beds; 4 surgical / 3medical beds), and have a dedicate critical care nursing staff. Most ICU nurses have at least 5-10 years of ICU experience. The usual staffing ratio of registered nurses (RNs) to patients in these ICUs was 1:3 additional to head nurses, were involved in the management of mechanically ventilated patients in both hospitals. The ICU's staffed by 4 attending physicians. The M/S ICU is managed by a team of consultant Intensivist , and 3 internist of resident physicians who rotated between the medical wards and the ICU. The SICU is managed and under the supervision of anesthesiologist, and 3 ICU fellows

of anesthetist resident physicians, who rotated between operating theatres and the ICU. In ours ICUs a dedicated RT not available, physicians and nurses presume the RT role to identify patients ready to wean from MV. ICUs at Palestinian hospital have the same system for staff and environment.

1.4. Nurse-driven ventilator weaning protocol/ Interventions

The protocol was presented to the ICU healthcare staff during a 2-week training period (twice a week, two hours per session)in both hospitals. They were trained on the weaning protocol, which included training programs before the start of the study. All nurses who are involved in the implementation of the protocol participated in the education program. There was also a medical entry in which we asked for a senior doctor to join us. Despite this being a nursing initiative, the medical intervention was important. Therefore, a multi-professional group of staff from different levels of experience and knowledge that represents the entire unit was formed. We educated staff on how to follow the weaning protocol (Appendix I1). This was carried out by presentations to staff nurses in the unit and ensuring they understood how to use the flowchart of protocol that was designed in order to illustrate the application of weaning protocol for ICU nursing staff (already included in chart tool of **Appendix III**). It also enabled them to ask questions that helped team members challenge the current practices and give nurses more autonomy over the weaning process. Approval for the use of the flowchart for weaning protocol was obtained from the consultant anesthetist, and copies of the protocol were laminated and fixed to the chart table at each bed in the ICU. A pilot period of one month was provided, in order for nurses to become familiar with the protocol and the implementation. Patients entered the protocol when their underlying indication for MV has resolved or significantly improved according to predetermined protocol entry criteria. At the beginning of the study, the protocol was initiated under physician supervision, but driven by the nurses, who evaluated each patient for weaning, SBT, and extubation each morning. The nursing staff who were responsible for the actual weaning of the patient. Later, the adherence for the protocol was improved and the nurses started leading the protocol independently based on their assessment of patients. The NLWP was subsequently introduced into an intervention group of a total of 34 adult patients (Rafidia Hospital n=19, Ramallah Hospital n=15).

1.5. Study protocol

Weaning protocol of this study was based on appraisal of literature of our systematic review of three previous studies (Hirzallah et al., 2018, in press). The review found that the most common weaning methods used in protocols included SBT with CPAP for patients who satisfied the eligibility weaning criteria for more than 24 hours (duration of SBTs ranged from 30 to 120 minutes through a ventilator circuit). Based on that we adopted Danker et al.'s (2013) study weaning protocol that used the most common of weaning methods for its weaning protocol. And after a protocol approval from anaesthesiologist and intensivist in clinical practice from our hospitals, quasi-

randomized controlled study was designed to meet our needs in hospitals.

Patient eligibility for the weaning procedure was identified by the charge nurse, who screening the mechanically ventilated adult patients every morning in the medical / surgical ICU's of multicenter trial. Screening was considered to start immediately after ICU admission. Patients had to meet all the following criteria: a) awake and able to follow simple commands; b) Vasopressors (equivalent to dopamine $\leq 5 \text{ mcg}/$ kg/min) and systolic Blood Pressure \geq 90 mm Hg; c) Heart Rate = 55 to 135 beats per minute; d) Respiratory rate < 35 breaths per minute; e) PaO2 / FIO2 ratio \geq 200) Positive end-expiratory pressure (PEEP) < 5 cm H2O (Appendix II). After completing a ventilator weaning readiness assessment, ICU nurses were provided sedation holiday or minimize sedation according the Richmond Agitation-Sedation Scale (RASS). The RASS is a 10-point scale, from 4 (combative) through 0 (calm, alert) to -5 (unarousable). The patient is assessed for 30 to 60 seconds in three steps, using discreet criteria (this process was already implemented during the physician-directed weaning period as documented in the medical records) hold tube feed, assess rapid shallow breathing index (RSBI) defined as: frequency divided by tidal volume, for 2-3 minutes and followed by a spontaneous breathing trial (SBT) if the RSBI was < 105.

The eligibility criteria for a SBT were the following: The SBT settings included pressure support 5-8 cm H2O and continuous positive airway pressure (CPAP) 0-5 cm H2O. Patient progressed through the weaning trial to decision to extubate if he/she met weaning tolerance criteria. Weaning tolerance criteria were as follows: a) Respiratory Rate < 35 breaths per minute; b) Heart rate between 55 and 135 beats per minute; c) Systolic Blood Pressure (SBP) between 90 - 170 mmHg; d) SpO2 \geq 92%; e) Patient showing no signs of diaphoresis, paradoxical respiration, retractions, nasal flaring, agitation, somnolence, or complaining of severe shortness of breath.

The eligibility criteria for a SBT were the following: For patients on intervention group (nurses- led protocol), the patients who tolerated a SBT for 30 minutes to 2 hours were extubated after confirming with an ICU physician. Extubation was performed when a nurse reported a patient's readiness for extubation. One weaning trial per 24 hours usually occurred. Before patient's enrolment nurses operated the mechanical ventilators according to a predesigned ventilator-weaning protocol for the intervention group (n = 34) to guide the assessment of weaning readiness and the weaning process for ICU patients.

1.6. Usual care of ventilator weaning

We gathering information, by recognition routine clinical practice of weaning care (non protocolized) in Palestinian hospitals and by reviewed hospital charts by health information system (HIS) at the hospitals. During the usual care (UC) period using; physician-led usual weaning care (February 2015- March 2017), the operation of the mechanical ventilator in the UC group, before establishment of the nurses led weaning protocol, was primarily led by the senior ICU physicians; almost started

during morning or work rounds. Physicians weaned patients according to their personal experience and preferences, thus there is no specific weaning criteria for monitoring. Physicians usually weaned patients using Fio2 50%, PEEP(5-8 cm H2O), pressure support mode (12-15 cm H2O) with or without Continuous Positive Airway Pressure. Screening for weaning readiness was twice daily: between 6am to 8am, and 5pm to 8pm, thus the decision to wean done only by ICU physicians (anaesthesiologist or intensivist). Here the role of ICU nurses get started for weaning patients in assessing for weaning readiness in the monitoring after the decision taken from the physicians to start weaning by daily stop sedation, check Spo2, and decrease FIO2, and should follow physicians in every step. Nurses just could control FIO2 parameter. The screening done by the physicians co-operative with nurses, thus the nurses could not initiate weaning, or advance the weaning process alone. Assessment included : a-level of consciousness (LOC), Vital sign(V/S) and MV parameter : (MAP (Mean arterial pressure)>60 (without looking exactly to systolic Blood Pressure), Heart Rate < 100 beats per minute, Respiratory rate < 30 breaths per minute, SPO2>90, FIO2< 0.50, Positive end expiratory pressure(PEEP)(5-8 cm H2O), pressure support (PS (12-15 cm H2O) (Appendix IV :chart tool for usual care (UC)). The decision to extubate after a successful weaning p process was also physician directed.

1.7. .Ethical considerations:

The study protocol was approved by Institutional Review Board (IRB) of An-Najah National University and permission to the study was obtained from the Ethical Committee of the Palestinian Ministry of Health. The study followed the World Medical, A. (2013). "World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects." JAMA310(20): 2191-2194.

1.8. Data collection

We collected data during the first day of ICU admission, including demographics; Age, gender, underlying disease, reasons for initiating mechanical ventilation, source of admission, and Acute Physiology and Chronic Health Evaluation (APACHE) II scores using data within 24 hours of ICU admission including Glasgow Coma Scale. Additional data was collected including; ICU interventions (vasoactive medications), duration of MV, weaning time, ICU and hospital LOS. In addition we recorded reintubation rate (the time and day of endotracheal reintubation considered unsuccessful discontinuation from MV within 48 hours after extubation), and the mortality rate.

1.9. Study outcomes

The study outcomes were duration of MV in days (defined as the period from the day of endotracheal intubation until the day of discontinuation of MV), and weaning time (defined as the time from identification of weaning readiness to successful discontinuation of mechanical ventilation), ICU LOS, hospital LOS, rate of reintubation, and hospital mortality.

1.10. Statistical analysis

Data are presented as mean and standard deviation (SD), medians and interquartile ranges (IQRs), or proportions, as appropriate. For continuous variables (four outcomes: duration of MV, weaning of MV, ICU LOS and Hospital LOS), non-normal distribution was observed for these outcomes, and a non-parametric test (Mann-Whitney test) was performed to compare outcomes according groups. Information about median and interquartile range (IQR);was used to describe the four outcomes, according groups. A p<.05 was considered statistically significant. The main assumption of non-parametric test is that we didn't assume any normal distribution of the data.

The categorical variables (Reintubation and mortality outcomes)are expressed as absolute (n) and relative (%) frequencies according groups, and Chi-Square test with Yates continuity correction was performed to evaluate the association between outcomes and groups. The probability of successful weaning over time for each study group was calculated according to Kaplan-Meier method and compared using the log rank test. Variables from each of the categories at baseline were examined using a Cox proportional hazards model. All analyses were conducted using IBM SPSS statistics 21 license.

2. Results

During the prospective study period (nurse-driven weaning), total ICU admission of 848 patients were screened for study participation, of whom 380 patients required MV from adult and pediatric, 147 adult Patients required MV, 108 adult Patients required MV for > 24 hours, (39 patients they required MV for < 12 hrs), Among the 108 eligible adult patients, 74 patients were excluded because: they died before initiation of ventilator weaning (died without extubation or weaning trial) (48 patients), or because they had tracheostomy on admission to ICU (10 patients), or converted to trachestomy (> 12 days on MV) (6 patients), and because transfer to other hospital without extubation (10 patients) (Fig. 1b). All patients weaned from MV and extubated in the NLWP had their weaning readiness assessment and SBT completed before extubation according to the protocol.

During the retrospective study period (physician-driven weaning), 974patients were admitted to the ICU, 460 patients required MV from adult and pediatric, 158 adult patients required MV, and 117 adult patient required MV for longer than 24 hours, (41patients they required MV for < 12 hrs). Among the 117 eligible adult patients, 83 patients were excluded because they died before initiation of ventilator weaning (died without extubation or weaning trial) (51patients), or because they had tracheostomy on admission to ICU (12patients), or convert to tracheostomy (> 12 days on MV) (7patients), and transfer to other hospital without extubation (13 patients). There were no differences in the proportions of patients represent within the combined treatment and control groups in both ICU's.



Figure 1b. Patient selection diagram

Table1b: Baseline	patient characteristic	s of the NLWF	' and usual care (UC)	
groups (Multicenter ICUs / PMC and Rafedia hosptials)				

Characteristic	NLWP (n =34)	UC (n=34)	Р
Characteristic	NLWP (n =34)	UC (n=34)	Р
Age (y), mean ± SD	56.0±20.3	47.4 ± 24.8	. 136
Female (%)	12(35.3)	10 (29.4)	.548
Source of admission(%)			
Emergency department	18 (52.9)	23(67.6)	.208
Operation room	9 (26.5)	6(17.6)	
In-patient floor	5(14.7)	1(2.9)	
Other ICU	2(5.9)	4 (11.8)	
Unit (%)			
MICU	15(44.1)	15(44.1)	1.00
SICU	19(55.9)	19(55.9)	
Reasons for initiating			.230
Mechanical ventilation(%)			
Acute exacerbation			
of chronic respiratory	4(11.8)	2(5.9)	
disease (Asthma, COPD)			
Postoperative state	16 (47.1)	11(32.4)	
Pulmonary edema	2(5.9)	1 (2.9)	
Pneumonia	2(5.9)	3(8.8)	
Sepsis	4 (11.8)	0(0.0)	
ARDS (RESP Failure)	2(5.9)	2(5.9)	
F.D, Head trauma	1(2.9)	5(14.7)	
Other (e.g Co -poisining,	3(8.8)	10 (29.4)	

Organophoshorus poisining,SAH,

GI bleeding, F.D, Head trauma)			
Underlying disease(%)	.167		
Chronic lung disease	11 (32.4)	6 (17.6)	
Gastrointestinal disease	8(23.5)	9 (26.5)	
Neuromuscular disease	1 (2.9)	6 (17.6)	
Renal disease	4 (11.8)	2 (5.9)	
Trauma	9 (26.5)	7 (20.6)	
Toxicity and poisoning	1 (2.9)	4 (11.8)	
APACHE II score,	21.2 ±7.0	18.5 ±7.3	.121
mean ± SD			
Vasoactive (%)	12(35.3)	10(29.4)	.795
Medication			

MICU indicates medical ICU; SICU, surgical ICU.

2.1. Demographic and clinical characteristics of patients

A total of 68 patients were mechanically ventilated through an endotracheal tube and required MV for longer than 24 hours included in the study, 34 patients in the prospective nurse -led weaning protocol group (NLWP)(case) and 34 patients in the usual care group (UC) (controls). Table 1b shows the demographic and clinical characteristics of all enrolled patients. There were no significant differences between the two treatment groups in age, underlying disease, or severity of illness upon ICU admission based on Acute Physiology and Chronic Health Evaluation II (APACHE II) score, source of admission, type of ICU (medical vs surgical), ICU admission diagnosis, and the use of vasoactive medication in ICU. There were 12/34 women in the NLWP group (35.3%) and 10/34 women in the UC group(29.4%, P = 0 .548). Mean (SD) of age in the NLWP group is (56.0±20.3 versus 47.4 ± 24.8 in the UC group. APACHE II score, 21.2 ± 7.0 in the NLWP group versus 18.4 ± 7.3 in UC.

Patients in the NLWP group were more likely to be admitted from operation room (9 patients, 26.5% vs 6 patients, 17.6%) in UC group, and In-patient floor (5/34(14.7%) in NLWP group vs 1/34(2.9%) in UC group. While Patients in the UC group were more likely to be admitted from Emergency room (23patients, 67.6% vs 18 patients, 52.9%). Nevertheless, there were no significant differences between the groups in source of admission (P = 0.208) (Table 1). There were no significant differences between the

two treatment groups in reasons for initiating of Mechanical ventilation; Patients in the NLWP group were more likely to have acute exacerbations of chronic respiratory disease (4/34(11.8%) vs 2/34(5.9%) in UC group, ARDS (2/34 patients, 5.9% in NWP vs 2/34 patients, 5.9%) in UC group. Patients with Postoperative state were 16/34 (47.1%) in NLWP group vs 11/34(32.4) in UC group, and to have pneumonia (2/34 patients, 5.9% in NLWP group vs 3/34 patients, 8.8%) in UC group. Pulmonary edema were (2/34 patients, 5.9% in NLWP group vs 1/34 patients, 2.9%) in UC group (Table 1).

Outcome	Nurse-Led weaning group (n=34)	Usual care weaning group (n=34)	р
Duration of MV (hours), median (IQR), (min-max)	24 (30), (24-110)	48 (48), (24-216)	0.034a
Weaning Time (hours), median (IQR), (min-max)	2 (2) (1-4)	4 (3), (2-13)	<0.001a
ICU LOS (d), median (IQR), (min-max)	5 (5), (2-17)	7 (6), (2-26)	0.033a
Hospital LOS (d), median (IQR), (min- max)	9.5 (10), (2-30)	10 (9), (2-39)	0.649a
Reintubation rate, n (%)	3 (8.8)	11 (32.4)	0.036b
Mortality, n (%)	6 (17.6)	10 (29.4)	0.391b

2.2. Effect of the weaning protocol Table 2b- Study outcomes measures of multicenter ICUs

a. Mann-Whitney test

b. Chi-Square test with Yates continuity correction

Duration of mechanical ventilation (hours): Patients assigned to the NLWP group had a shorter median overall duration of mechanical ventilation a 24 hours (IQR=30hrs), (min-max =24-110) compared to UC group, median= 48hrs, (IQR=48hrs), (min-max =24-216); p = 0.034) (Table 2b).

Weaning time (hours): There was a significant difference in the weaning time according group, with median=2 hours (IQR=2hrs) (min-max =1-4) in the NLWP group and median=4 hours(IQR=3hrs) (min-max = 2-13) in the UC group (p=0.001) (Table 2b).

Intensive care unit length of stay(days): The ICU LOS median was 5 days (IQR=5days) (min-max =2-17) within NLWP group and 7days(IQR=6 days) (min-max = 2-26) in the UC group (p=0.033) (Table 2b).

Reintubation rate(%):There was a significant association between reintubation rate and group: the proportion in NLWP group was 3/34 (8.8%) compared to 11/34 (32.4%) in the UC group (p= 0.016) (Table 2b).There were no statistically significant differences in the other outcomes, including hospital LOS and Hospital mortality (Table2b).

ICU Type	Outcome	Nurse-Led weaning protocol group (n=15)	Usual care group (n=15)	р
	Duration of MV (hours), median (IQR), (min-max)	42 (48) (24-120)	50 (30) (24-179)	0.137a
MICU	Weaning Time (hours), median (IQR), (min-max)	2 (2) (1-4)	4 (2) (2-12)	0.001a
	ICU LOS (d), median (IQR), (min- max)	5 (3) (2-11)	7 (5) (3-12)	0.389a
	Hospital LOS (d), median (IQR), (min-max)	6 (6) (2-30)	9 (7) (2-23)	0.902a
	Reintubation rate, n (%)	1 (6.7)	11 (40.0)	0.080b
	Mortality, n (%)	4 (26.7)	5 (33.3)	1.000b
ICU Type	Outcome	Nurse-led weaning protocol group (n=19)	Usual care group (n=19)	р
SICU	Duration of MV (hours), median (IQR), (min-max)	24 (22) (24-72)	48 (26) (24-216)	0.154a
	Weaning Time (hours), median (IQR), (min-max)	1.5 (2) (1-3)	4 (3) (2-13)	<0.001a
	ICU LOS (d), median (IQR), (min- max)	5 (6) (2-17)	7 (9) (2-26)	0.070a
	Hospital LOS (d), median (IQR), (min-max)	11 (13) (2-30)	13 (14) (4-39)	0.644a
	Reintubation rate, n (%)	2 (10.5)	5 (26.3)	0.405b
	Mortality, n (%)	2 (10.5)	5 (26.3)	0.405b

Table 3b- Study outcomes measures in MICU and SICU

a. Mann-Whitney test

b. Fisher's exact test

There is no statistically significant differences in each of outcome; Duration of MV, ICU LOS, Reintubation rate, Hospital LOS and Hospital mortality, there is only significant difference between groups for weaning time, MSICU; with median=2 hours (IQR=2hrs) (min-max =1-4) in the NLWP group and median=4 hours(IQR=2hrs) (min-max = 2-12) in the UC group (p= 0.001), in SICU with median=1.5 hours (IQR=2hrs) (min-max =1-3) in the NLWP group and median=4 hours(IQR=3hrs) (min-max = 2-13) in the UC group (p= 0.001), (Table 3b). The authors hav been speculate that the small sample size could be affect on other outcomes measures.

Kaplan-Meier plots of the probability of successful weaning over time for each group; in the NLWP and UC group are shown in Figure 2b. Analyses indicated no significant difference in probability of remaining on MV over time between the NLWP and UC groups was found (log-rank test: p=0.243). Survival analysis was performed considering: Duration of MV as follow-up time, and Successful intubation as event of interest.



Figure. 2b- Kaplan-Meier plots of the probability of remaining on MV over time in the NLWP and UC group.

Cox proportional hazards regression analysis identified 2 factors that independently predicted the duration of MV before successful weaning, gender and age (Table 4b). The adjusted hazard of successful weaning was statistically higher in female than male (HR=5.76; 95% confidence interval, 1.45-22.9; p=0.013). The other predictor of weaning from MV was age (HR=1.05; 95% CI, 1.01-1.08; p=0.009)(Table 3).

There's no statistically significant in the adjusted rate of successful weaning in the NLWP and UC , but the adjusted hazard ratio(HR) of weaning from MV was higher in the UC group than the NLWP group, (HR= 2.02; 95% Cl,0.41-9.82; p=0.385) (Table 4b). For other predictors of weaning from MV: APACHEII score use of vasoactive medications in ICU, the adjusted hazard of successful weaning was not statistically significant.

Variable	Adjusted			
variable	HR 95% CI		р	
Group				
Nurse-led weaning protocol	1	-	-	
Usual care	2.02	0.41-9.82	0.385	
Use of vasoactive Medications				
Νο	1	-	-	
Yes	1.02	0.27-3.80	0.980	
APACHE score	0.98	0.88-1.09	0.704	
Age	1.05	1.01-1.08	0.009	
Gender				
Male	1	-	-	
Female	5.76	1.45-22.9	0.013	

Table 4b- Independent predictors of duration of MV using Cox proportionalhazards regression analysis

Discussion

Our prospective, quasi-randomized study with comparison to retrospective data (historical control) of mechanically ventilated adult patients for more than 24 hours in a medical and surgical ICU demonstrated that nurse-led weaning protocol showed shortened in median duration of MV, shorter in weaning time, decrease in median duration of ICU LOS, and significantly lower in reintubation rates compared to UC groups. Our protocol was simple, easily to implement, and required no additional staff and minimal specific training of RNs. Our findings in line with our systematic review of previous three studies (Hirzallah et al., 2018, In press) that showed a significant difference in reducing the duration of MV, weaning time, and ICU LOS in favour of nurse-led weaning protocols(NLWP) for critically ill adult patients compared to UC and that the protocols easy to implement, safe, and accepted by the ICU health staff. Moreover, the reduction in the MV duration in our findings is in accordance previous studies of directed weaning protocol that was managed by nurses with and respiratory therapists (RTs) (Dries et al., 2004; Ely et al., 1996; Kollef et al. 1997; Marelich et al., 2000; Plani et al., 2013; Price, 2001). This is in contrary with (Krishnan et al.2004) study that found no significant in duration in MV due to the high levels of physician staffing in closed ICU that may influenced on the efficiency of ventilator weaning protocols driven by non-physicians, and related to Hawthorne

effect; that physicians, nurses, or RTs were aware of the study in progress and changed their practice for ventilator management.

The significant reduction in weaning time that showed in our study, in accordance with (Ely et al., 1996; Roh et al., 2012) studies. Thus Roh et al. (2012) study reported that a significant reduction in weaning time from mechanical ventilation of weaning protocol; that established by nurses; was defined as the time from enrolment (initiation of weaning) to successful discontinuation of MV. Furthermore, there were a significant reduction in ICU LOS in patients receiving NLWP in our clinical trial. This is similar to the findings of a study by (Danckers et al. 2013; Tonnelieret al. 2005), while this is contrary with findings of studies (Ely et al., 1996; Grap et al., 2003; Kollef et al., 1997, Krishnan, 2004; Planiet al., 2013; Roh et al., 2012) that reported no significant decrease in ICU LOS. Interestingly, reintubation rate had significantly lower in the NLWP than UC groups in our study compared to other studies that found the rate of re-intubation was similar between the groups (Danckers et al. 2013; Planiet al., 2013; Roh et al., 2012;Tonnelieret al. 2005). But this is in accordance with (Ely et al., 1996) study that found in the intervention of their group had fewer complications than the controls including fewer reintubations rate and had significantly reduction. Thus the decrease in reintubation rate resulted in decrease in ICU LOS and decrease in the complications that will arise from the consequences of reintubation or overlap intubation, as well as safe for the patients. Therefore, according to (Fulbrook et al., 2004) study of developing a Network protocol: nurse-led weaning from ventilation, found that the use of a protocols allow the staff to identify on the earliest opportunity for any patient capable of breathing spontaneously, to optimise extubation timing, and avoid both reintubation and overlong intubation, and reducing weaning time, thus the results evidenced that the nurses involvement in weaning process is beneficial. And this is agreement with our results. Furthermore, we found that the use of nurse-led protocols to guide weaning had no effect on other adverse events, including hospital LOS, and hospital mortality. These findings are in accordance with the findings of (Ely et al., 1996; Danckers et al., 2013; Kollefet al., 1997); Krishnan et al., 2004; Plani et al., 2013; Roh et al., 2012; Tonnelieret al. 2005). While this is in contrary with the results of meta analysis of our systematic review that found the pooled data had a significant reduction in hospital LOS.

According to **Cox proportional hazards regression analysis**, although, the adjusted rate of successful weaning was not statistically significant in nurse led weaning group vs the physician-led care weaning group (UC), but the adjusted **hazard ratio** of weaning from MV was **higher** in the physician-led care weaning group(UC) than the nurse led weaning group, we believe, that a small sample size was a major cause that affected on the results of adjusted rate of successful weaning

we recommended for larger sample size in the future study. Similar to our study, Roh et al. (2012) did not find an association between weaning protocol and successful

weaning. They suggested related to a small sample size and duration of respiratory failure in their study.

In ours ICUs a dedicated RT is not available, physicians and nurses presume the RT role to identify patients ready to wean from MV and to assist in the weaning trial as in some ICUs of previous studies (Danckers et al. 2013; Roh et al., 2012;Tonnelieret al. 2005). The primary benefits of our weaning protocol was that the nurses, are able o respond to changing patient status by making suitable amendment of FIO2, PEEP, and inspiratory pressure (pressure support), and in decision making accordingly, thus they daily contact with ICU patients, and they will expedite weaning process. This is in agreement with Roh et al., 2012 ; Rotello et al., 1992) studies that found the nurses , adhere to directed protocols, and can successfully wean patients from MV, cause they are more readily available than physicians. The intervention was intended to simulate our hospitals to allow the nurses to operate weaning process of mechanical ventilator, thus in our ICUs we do not have full-time intensivists, or anesthesiologist, to cover the ICU's, so the weaning times under these circumstances were prolonged because the physician's schedule does not allow time to respond immediately to individual patient needs.

The safety measures were considered during the study protocol to prevent complications: the nurses who were actually implementing the protocol were being supervised by the charge nurse and physician.

Limitation

The main challenges in our study was that the small sample size as it was difficult to find large number of participants that fit the eligibility criteria of our study for patients within one year during the PhD study period. The results should be interpreted with caution.

Other limitation of our study is that the NLWP group ICU nurses were aware the study in progress and is being observed, and that might have motivated them to be more compliant and adhere to application of the protocol. This could cause possible bias and influence the study results.

Finally, that we used historical controls, thus the allocation process for retrospective data for the UC group was based on medical records in our quasi- experimental, making it potentially subject to selection bias. However in other studies studies (Danckers et al. 2013 Krishnan, 2004;Tonnler 2005), found that ventilator weaning studies with historical controls have the slight advantage over randomized studies in eliminating the risk of crossover effect and potential bias of physicians or nurses during the physician-driven weaning in influencing study design and results.

Conclusion: Our results clearly indicate that weaning protocol administered by nurses was associated with shorter duration of MV, shorter weaning duration, shorter ICU
LOS and less reintubation rate for critically ill adult patients compared to UC and the protocol was simple easy to implement, and safe for the patients. Implementation of nurse-led weaning protocols had better outcomes that can help better management of ICU patients in Palestine. We believe that our study provides further evidence of nurses-led weaning protocol that have a major impact on weaning patient outcomes without additional staffing. Implications for future research include a need for larger sample in future study with randomized controlled studies to gain more evidence in support of nurse-led weaning protocols, and that a change in this clinical approach is warranted.

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CHAPTER VII - Discussion and Conclusion

- 7.1- Overview of the project findings
- 7.2- Discussion
- 7.3- Conclusions
- 7.4- Strengths and limitations and of the study design
- 7.5- Implications for clinical practice and future directions

In this chapter, we describe the main overview of the study findings, discussion, and address the main conclusions of this research project, limitations and strengths of the study design. Finally, we present the relevance and implications for clinical practice and future research in this field.

7.1- Overview of the project findings

In the first study entitled "A systematic review of nurse-led weaning protocol for mechanically ventilated adult patients: a meta-analysis" (Chapter IV), the results of this review evidenced that the NLWP reduces the duration of MV, weaning time, and ICU LOS and affect other outcomes for critically ill adult patients compared to usual physician-led care. In the meta-analysis, the pooled data from three included studies illustrate a statistically significant difference in favor of NLWPs for reducing the duration of MV and ICU LOS (Danckers et al., 2013; Roh et al., 2012; Tonnelier et al., 2005). Three included studies demonstrated that the NLWP reduced the duration of MV, with p=0.001. The mean MV duration was reduced by 1.69 (range from 2 to 6 days) (Danckerset et al., 2013; Rohet et al., 2012; Tonnelieret et al., 2005). One study reported a significant decrease in weaning time as an outcome (p=0.010) (Roh et al., 2012).

Data from the three included studies demonstrated that the NLWP reduced the duration of MV with p =0.00001, and the mean ICU LOS was reduced by 2.04 days (Danckerset et al., 2013; Rohet et al., 2012; Tonnelieret et al., 2005).Two of the three included studies demonstrated that the NLWP reduced the length of hospital stay with P=0.001; the mean hospital LOS was reduced by 2.9 days (Danckerset al., 2013; Rohet al., 2012).

The second study entitled: "Critical Care Nurses ' Perceptions Towards Nurse-Led Weaning Protocol From Mechanical Ventilation In Intensive care units in Palestine-A qualitative Study (Chapter V) demonstrated the following results. The content was thematically categorized, and six themes emerged: (i) agreement/support: (ii) increased awareness; (iii) nursing expertise and qualifications for leading weaning protocols; (iv) improved patient outcomes; (v) inter-professional collaboration; and (vi) Barriers to nurse-led weaning. The findings demonstrate a positive impression and acting toward NLWP from health professionals among Palestinian hospitals.

The third study was a quantitative quasi-randomized study **entitled** "The impact of critical care nurse-led weaning protocol on outcomes of MV for critically ill patients among Palestinian hospitals" (Chapter VI). Our results demonstrated that the NLWP group showed a decrease in median duration of MV, shorter weaning time, decrease in median duration of ICU LOS, and significantly lower reintubation rates compared to UC group. As the following:

Duration of mechanical ventilation (hours): Patients assigned to the NLWP group had a shorter median overall duration of MV at 24 hours (IQR=30hrs), (min-max =24-110) compared to UC group, median= 48hrs, (IQR=48hrs), (min-max =24-216); (p= 0.034).

Weaning time (hours): There was a significant difference in the weaning time according to the group, with median =2 hours (IQR=2hrs) (min-max =1-4) in the NLWP group, and median =4 hours (IQR=3hrs) (min-max = 2-13) in the UC group (p=0.001) (Table 2).

Intensive care unit length of stay (days): The ICU LOS median was 5 days (IQR=5 days) (min-max =2-17) within NLWP group, and 7 days (IQR=6 days) (min-max = 2-26) in the UC group (p=0.033) (Table 2).

Reintubation rate (%): There was a significant association between reintubation rate and group type. The proportion in NLWP group was 3/34 (8.8%) compared to 11/34 (32.4%) in the UC group (p= 0.016) (Table 2).There were no statistically significant differences in the other outcomes, including Hospital LOS and Hospital mortality.

7.2-Discussion

Based on these findings of three studies in our research project, we found that our prospective quasi-randomized study results (study III) are in line with our systematic review meta-analysis (study I) (Hirzallah et al., 2018, in press). The results showed a significant difference in reducing the duration of MV, weaning time, and ICU LOS in favor of NLWP for critically ill adult patients compared to UC and that the protocol was simple, easy to implement, safe, and accepted by the ICU health staff. Furthermore, the results in study (III) found a significantly lower reintubation rates compared to UC groups. However, the meta-analysis showed a significant difference in reducing hospital LOS in favor of NLWP.

Duration of MV

The reduction in the duration of MV that was found in study (III) and study (I) of our findings was in accordance with previous studies of directed weaning protocol that was managed by nurses and respiratory therapists (RTs) (Dries et al., 2004; Ely et al., 1996; Kollef et al. 1997; Marelich et al., 2000; Plani et al., 2013; Price, 2001). This is contrary with Krishnan et al. (2004) study that found no significance in duration in MV due to the high levels of physician staffing in closed ICU.

Weaning time

The significant reduction in weaning time that showed in study (III)and study (I) of our results in accordance with (Ely et al., 1996; Roh et al., 2012) studies.

ICU LOS

Furthermore, there were a significant reduction in ICU LOS in patients receiving NLWP in study (III) and study (I). This is similar to the findings of a study by Smyrnioset al. (2002), while this is contrary with findings of studies (Ely et al., 1996; Grap et al., 2003; Kollef et al., 1997, Krishnan, 2004; Planiet al., 2013; Roh et al., 2012) that reported no significant decrease in ICU LOS.

Reintubation rate

Moreover, in study (III) we found a significantly lower in reintubation rates compared to UC groups and this was not in line with study (I), Interestingly, reintubation rate had significantly lower in the NLWP than UC groups in our study compared to other studies that found the rate of re-intubation(not significantly) was similar between the

groups of study (Danckers et al. 2013; Planiet al., 2013; Roh et al., 2012; Tonnelieret al. 2005). But this is in accordance with (Ely et al., 1996) study that found in the intervention of their group had fewer complications than the controls including fewer reintubations rate and had significantly reduction compared to control group.

Hospital LOS

Furthermore, in study (III) we found that the use of NLWPs to guide weaning had no effect on hospital LOS. These findings are in accordance with the findings of Ely et al. (1996), Danckers et al. (2013), Kollefet al. (1997), Krishnan et al., (2004), Plani et al. (2013), Roh et al. (2012), and Tonnelier et al. (2005). However, the results are in contrast with the results of the meta- analysis of our systematic review in study (I) that found the pooled data had a significant reduction in hospital LOS.

The overall results of the investigation that was demonstrated in study (II) supported our results in study (III) and study (I) of the ICU NLWP in Palestinian ICUs. Themes reiterated that such protocol led to improved patient outcomes, the prioritization of patient safety, enhancement of inter-professional communication, as well as an increase in professional competency. From the nurses' perceptions. Furthermore, through the nurses' implementation of the weaning protocol in the current study, we found that the weaning protocol contributed to raise the efficacy of nurses' role in ICUs by raising awareness and increasing professional competency among ICU nurses. This is in accordance with Hansen et al. (2008), who studied in a Norwegian ICU how physicians perceived protocol-directed weaning by nurses. The results demonstrated that the physicians accepted the protocol, and had a positive influence on weaning, and enhanced efficiency of nurses (Hansen et al., 2008). A related study found that ICU nurses perceived the protocol as useful and allowed the nurses to act in the absence of a physician (Hansen and Severinsson, 2007). Another study by Haugdahl et al. (2014) found that increasing acknowledgment and awareness of the ability and role of nursing staff may promote inter-professional collaboration and ultimately improve patient care.

Furthermore, nurses referred to the positive benefits they gained from having a structured guide of weaning protocol. The use of a nurse-directed weaning protocol increased the nurses' knowledge and sense of autonomy. Through education and use of the protocol, nurses gain comprehensive and valuable knowledge of respiratory assessment and mechanics which allows them to actively contribute to positive outcomes for patients. This is consistent with Blackwood et al., (2007), Blackwood et al. (2004), and Grap et al. (2003) studies. Weaning decisions are often a part of nursing care in nature. Nursing staff stressed that ICU nurses should lead weaning protocols because they have the expertise and direct contact with I CU patients, and they can titrate ventilation parameters accordingly. This is in accordance with Roh et al. (2012) study in which nurses were able to respond more rapidly to changing patient status by making suitable adjustment to respiratory parameters, allowing a

more rapid weaning because they are responsible for fewer patients than physicians. A similar observation was reported by Haugdahl et al. (2014) demonstrating that nurses have greater autonomy regarding decisions on MV, including increased influence and collaborative interaction with physicians, as perceived by nurse managers.

Based on our recent investigation among Palestinian hospitals, studies (II) and (III) have shown that weaning protocols administered by nurses for mechanically ventilated patients were safe and easy to implement. These findings are in accordance with Hansen et al. (2008). The nurses also in the current study underlined the importance of effective communication and collaboration between physicians and nurses. These findings are in line with Hansen and Severinsson (2007) who emphasize that in order to improve patient safety, health-care providers must support team learning through frequent sharing of insights and concerns throughout organizational systems, effective collaboration among nurses and physicians, open communication and shared team goals which are known to improve the quality of care for patients (Haugdahl et al., 2014). Based on Hansen & Severinsson (2007) study, each professional in the team has special expertise that can lead to improve patient management.

7.3- Conclusion

Nurse-led weaning protocols can be implemented safely and effectively and have a major impact on patients' outcomes for critically ill adult patients. Remarkably, the results evidenced that the weaning protocols led by critical care nurses resulted in reductions in the duration of MV, weaning time, ICU LOS and reintubation rates compared to UC. Results also showed that the protocol was simple, easy to implement, and accepted by the ICU health staff, with no additional staff required and minimal specific training of ICU nurses. In this research, the ICU nurses had a positive overall impression and support for NLWP in ICUs and found it viable for applicability among Palestinian ICUs.

Hence, based on our findings in this thesis, the nurses' perceptions and through the implementation of a NLWP, that the protocol contributed to the increased efficacy of nurses' role in ICUs, by raising awareness and increasing professional competency among ICU nurses. This is ground to why we defend that a NLWP should be implemented by nurses through structured programs in ICUs among Palestinian hospitals in the Palestinian health system.

7.4- Strengths and Limitations of the study design

Our study is unique and has several strengths. First, we believe that our quantitative study is unique because it is one of only three published studies that compare NLWP with usual physician-led care. Most previous studies that compared non-physician-driven with physician-driven weaning used RTs or a combination of nurses and RTs, rather than ICU nurses alone to guide weaning patients from MV. Furthermore, our study is the first study of this kind conducted in Palestine and provides further

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evidence of NLWP that can contribute to better outcomes of ICU patients. In addition, our systematic review and meta-analysis was the first synthesis of NLWPs compared with usual physician-led care, and it provides further assurance that ICU nurses alone can guide weaning from MV. We believe that our study provides further affirmation that major medical therapy can be delegated to nurses alone while ICU physicians can perform other duties in the ICU. Simultaneously, and because of this particularity, we consider that this study is even more necessary, useful and valid, as it provides an innovate contribution to nursing.

However, and beyond the strengths of this study, there are a few overall limitations that need to be considered. The challenges in our systematic review were that only three studies of NLWPs were included in this review, and only one study was an RCT, thus the results should be interpreted with caution. Furthermore, the protocols used in the three studies were varied. The main challenge in the quantitative study was that the small sample size as it was difficult to find large number of participants that fit the eligibility criteria of our study for patients within one year during the PhD study period. Another limitation of the study is that the NLWP group ICU nurses were aware the study is in progress and is being observed, and that might have motivated them to be more compliant and adhere to the application of the protocol. This could cause possible bias and influence the study results. Furthermore, in our quasi-experimental study, the use of historical controls for retrospective data for the UC group was based on medical records, making it potentially subject to selection bias. The limitation for the focus group study was the small number of participants in the groups due to their workload and a shortage of nurses in the unit. Another limitation for the focus group methods is that it can be criticized for the dominance of some voices over others, with potential distortion of the views of the group. The facilitator attempted to overcome this by encouraging participation from all of the group members and checking out responses from more vocal participants.

7.5- Implications for clinical practice and future research

This study provides further evidence about nurses' important role in ICUs, and nursing autonomy in decision making for improved outcomes of mechanically ventilated critically ill adult patients. Our study, given the uniqueness of Palestinian nursing culture particularly in the critical care context, can contribute to better outcomes of ICU patients. The use of weaning protocol by nurses is a relevant feature, probably the most meaningful of this study. In fact, based on our findings, we consider the use of a weaning protocol led by nurses may contribute to the effective implementation of this methodology in practice, without additional health staff and costs to the healthcare system, reason why we recommend its inclusion in health policies. Moreover, the combination of methodologies, focusing on the perceptions and experiences of the participants, and satisfaction, brings a better profit to this subject. This can be achieved through the integration of this methodology in practice, which requires the interaction and relational dimension nuclear in nursing, contributing to the development of the

critical care nursing field.

Based on our findings we can also presume that the implementation of the weaning protocol as a common weaning plan in practice can provide a standardized weaning process that may positively reduce weaning trials and delays, and therefore improve patient outcomes. Thus, systematic weaning protocols based on evidence can reduce variations in clinical weaning practices and offer an internationally standardized process. Also, NLWPs are perceived by health staff as likely to have positive effects on collaborative decision making for health teams related to ventilation weaning. Standardized weaning protocols led by nurses were effective in reducing MV time and ICU and hospital LOS, have a positive impact on weaning outcomes, are safe and viable to implement among Palestinian hospitals.

For future research, there's a need for extensive randomized controlled studies to gain more evidence in support of NLWP and effective durations of MV, ICU LOS, and hospital LOS, and a change in this clinical approach is warranted. A more abundant line of investigation in further research seeking powerful predictors of successful weaning or extubation, that decrease the duration of MV without substantially increasing rates of reintubation or failed extubation. Nursing research is an important means of improving nursing skills, which in turn will strengthen the nurse's voice in the inter-disciplinary team and enhance patient care. The health team recommends the following: health staff should be involved in developing, evaluating, and revising weaning protocols as new evidence emerges; constant re-evaluation and modification of the protocol based on evidence are essential to successful weaning and improving patient outcomes; critically ill patients need constant care and evidence-based systems of practice. Future studies should evaluate the differential impact of protocols in different types of patients and in ICUs with different organizational structures (e.g., open versus closed units, and teaching versus community hospitals). The influence of different protocols and their impact on ICU and hospital LOS and costs are important future considerations.

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(Appendix I) Focus group interview guide

The focus group is method to provide the participants with an opportunity for discussing their perceptions of protocol directed- weaning and allow the researcher to observe group interaction(nurse and physician).Group discussions provide direct evidence about similarities and differences in the participants' opinions and experiences (Morgan, 1997).

The key question is the Nurses & Physician ' perception (attitudes and beliefs) of nurses- led weaning protocol.

• Main objective of this study is to:

Identify the attitudes of health staff toward the nurse driven weaning protocol in intensive care unit among Palestinian governmental hospitals.

- Minor objectives of this study is to:
- 1. Recognize the participants the **initial thoughts** on hearing the term '**weaning protocol**' and "**Nurse -led protocol**"
- 2. Promote the awareness and acceptance of the study among physicians and ICU nurses in Palestine, and to promote communication between each others

I'm a teacher at An-Najah National University at faculty of medicine and health sciencesnursing department, PhD candidate at University of Porto/Portugal. I have to write a thesis project as a university requirement overseas. The project describes a scientific study on the Nurses and Physicians' attitudes toward the nurse driven weaning protocol in intensive care unit among Palestinian hospitals. your cooperation will be vey appreciated.

It will be used to collect information on the subject of the study. We would be very grateful to answer the questions. We declare that the information to be provided to us will only be used for scientific research.

Researcher signature: ----- Date-----

Participant signature:-----Date-----Date------

.....

Thank you for your cooperation

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• Demographic data

Please circle if you are as a fellow:

- 1. Gender : Male Female
- 2. Age:
- 3. Specialization: a. Nurse b. Physician
- 4. Nurses grades: 1- Staff nurse 2-Charge nurse
- 5. ICU attending physician: 1- Surgery 2-anesthetist
- 6. Qualification: 1-Bachelor 2-Master
- 7. Range of experience in ICU:
 - a.1-5 years b.6-10 years c.11-15 years d.16-20 d. Above

Interview guide (Open end questions):

- 1. Who decides when a patient is ready to wean?
- 2. Can you describe the procedures of weaning patients from mechanical ventilation: What is the doctors role? What is the nursing role ?
- 3. Do you believe that ICU nurses are capable of carrying/leading protocols for ventilator weaning? (TECHNICAL CAPACITY/CLINICAL JUDGMENT).
- 4. Do you think that nurse-led protocols are applicable or would be applicable in Palestinian hospitals? (EXPERIENCE)
- 5. Do you think it's safe to let ICU nursing staff perform protocol driven ventilator weaning (SAFETY)
- 6. Do you think that a nurse-driven protocol guided ventilator weaning would help the ICU nurses to identify patients ready for ventilator weaning earlier (EARLIER IDENTIFICATION/ CLINICAL JUDGMENT).
- 7. Do you believe that a nurse-driven protocol guided ventilator weaning could shorten ventilator weaning time (SHORTER WEANING TIME)?
- 8. Do you think that ICU nurses should have a nurse-driven guided ventilator weaning protocol?, It is overall a positive thing? (OVERALL IMPRESSION)

Appendix (II): Assessment tool for weaning readiness and weaning tolerance (Mechanical Ventilation Weaning Protocol):



Appendix III: Chart tool for nurses led weaning protocol(NLWP)



Impact of Nurses-Led Weaning Protocol on Outcomes of Mechanical Ventilation for Critically III Patients Among Palestinian Hospitals.

PhD Student: Fatima Hirzallah RN, MSc, CNS

chart tool

For critically ill adults weaning from mechanical ventilation by using NLWP at Palestinian hospitals (intervention group):

• Patients characteristics:

A) Demographic variables:

1-Age (y) :-----

2-Gender: a-Female

b-Male

d-Other ICU

3-Source of admission:

a-Emergency department(ER) b- Operation room(OR)

c- In-patient floor

other :-----

5 -ICU type : surgical ICU

6-ICU diagnosis:-----

7-Reasons for initiating mechanical ventilation(MV)------

- Date of start MV:-----Time:-----

Flow Sheet of Assessment Tool for Ventilator Weaning Readiness and

Screen 1* Date: Time:-				
All patients receiving mechanical ventilation are assessed by using screen 1 every day, and				
results are documented on the Ventilator Weaning Readiness Screen.				
Parameter Result				
YES NO				
1-Awake and able to follow simple commands				
2-Off sedation ?				
2-Hemodynamics stable? according to :				
- Vasopressors (equivalent to dopamine $\leq 5 \text{ mcg/kg/min}$) and systolic Blood Pressure ≥ 90				
mm Ha				
-Heart rate between 55 and 135 beats per minute				
-Respiratory Rate <35 breaths per minute				
3. PaO2/FIO2 ratio ≥200? Or (SaO2 ≥90 % on FIO2 of 0.40 or less)?				
4. Positive end-expiratory pressure (PEEP) < 5 cm H2O ?				
If <u>NO</u> to any question, <u>STOP</u> ! Otherwise if (<u>yes</u>) , ALWAYS proceed to <u>screen</u> 2				
Screen 2*: Rapid Shallow Breatning Index (RSBI) = Respiratory rate (breatns/min) ÷Tidal volume (Liters)Measure Rapid Shallow Breathing Index (RSBI) after brief 2-3 minutes on Pressure support(PS) = 5-8 cm H2O and continuous positive airway pressure (CPAP) = 0-5 cm H2ORSBI = f/Vt RSBI is < 105vesNo				
If <u>YES</u> , proceed to spontaneous breathing trial. If <u>NO</u> , rest patient until the next day and reassess starting with screen 1 • Spontaneous breathing trial*(SBT):30-120minutes:				
<u></u>				
Pressure support (PS) = 5-8 cm H2O and (CPAP) = 0-5 cm H2O (Spontaneous ventilation				
mode (SPV) + PEEP = 0-5 cm H2O)				
-TOLERANCE OF SBT Yes No				
-Respiratory Rate <35 breaths per minute				
-Heart rate between 55 and 135 beats per minute				
-Systolic Blood Pressure (SBP) between 90 - 170 mmHg				
-SpO2 ≥ 92%				
-Patient showing no signs of diaphoresis, paradoxical respiration, retractions, nasal flaring,				
agitation, somnolence, or complaining of shortness of breath yes No				
If spontaneous breathing trial is successful, get physician approval for Extubation.				
Date Time				
If spontaneous breathing trial is unsuccessful, rest patient until the next day and begin with				
<u>Reason for not extubating, if all criteria met:</u>				

WeaningTolerance for Adult patients on ET > 24hrs

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Frequency of weaning attempts (how many times of weaning attempts):					
Re- intubation, Time: Date					
-Date of discharge from ICU:					
-Reason of discharge:					
a- Go home	b-Transfer to ward (In-patient floor)				
c-Transfer to other ICU	d-Transfer to other hospital				
e-death					
-Date of admission to the hospital					
-Date of discharge from the hospi	tal:				

-

Appendix IV: Chart tool for usual care(UC)



Impact of Nurses-Led Weaning Protocol on Outcomes of Mechanical Ventilation for Critically III Patients Among Palestinian Hospitals

PhD Student: Fatima Hirzallah RN, MSc, CNS

chart tool

For critically ill adults weaning from mechanical ventilation by using usual care(UC)at Palestinian hospitals (control group):

• Patients characteristics:

A) Demographic variables:

1-Age (y) :-----

2-Gender: a-Female b-Male

3-Source of admission:

a-Emergency department(ER)

b- Operation room(OR)

c- In-patient floor

d-Other ICU

other :-----

5 -ICU type : surgical ICU

6-ICU diagnosis:-----

7-Reasons for initiating mechanical ventilation(MV)------

- Date of start MV:-----Time:-----

B) Physiological variables and MV parameters for weaning criteria:

Assess- ment	Oxygen- ation	Other respiratory factors	Inflammat- ory	Cardiov-asc ular	Neurolog -ical (LOC)	Medication	Other:
Screening for weaning readiness doing: Twice daily 6am-8am 5pm-8pm	-FIO2: Hgb: - - ABG's PH: PaO2: PaCO2: Elec- trolyets: -K+: -Na + :	MV mode: - (PEEP)= (cm H2O) -RR: TV: Other	-Temp:	Systolic Blood Pressure: -MAP: HR(b/m): CVP: Other:	Patient awake and obey Command Responsive to stimulus GCS:- Ramsey sedation score or RAAS:	vasoactive or inotropic agents	(e.g: Cough and gag reflex active : -Adequate cough. Suctioning <2/hour. Cuff leak test (inspirator and/or expiratory air leaks after cuff deflation -Urine out put -chest x ray result -Feeding: Parenter- al tube etc) Early mo- balization

Screen	Weaning method	Extubation criteria
Twice daily	SBT using either flow-by, PSV, or a T-piece according to the case	1-Confirming with an ICU physician
6am-8am	Spontaneous breathing trial (SBT):	
	On Pressure support (PS) = 12-15cm H2O and	2-Only performed by
5pm-8pm	Positive end-expiratory pressure (PEEP) < 5 cm H2O	physicians, monitored the patient for 2 hrs after Extubation
	a-Level of consciousness (LOC)	
Here the role	b -V/S :	
of ICU nurses	1. (MAP (Mean arterial pressure)>60 (
get started	without looking exactly to systolic Blood	
for patients	Pressure),	
monitoring	2. Heart Rate < 100 beats per minute	
	3Respiratory rate < 30 breaths per minute	
	4ABG's within normal values	
	5. SPO2>90	
	6FIO2< 0.40	
	2 - using a 1-piece $(7 - 8 L / M)$ for 2-4 hrs,	
	depend on case	

-Time of extubation :----- date of Extubation -----

-Frequency of weaning attempts (how many times of weaning attempts): -------

-Re- intubation , Time------ date:-----

-Date of discharge from ICU:-----

-Reason of discharge:

a- Go home

c-Transfer to other ICU

b-Transfer to ward (In-patient floor)

d-Transfer to other hospital

e-death

Date of admission to the hospital ------

-Date of discharge from the hospital:-----

(Appendix V a) Consent Form

I, the undersigned: _____

Assure that it has been read and to clarify the request to participate in this study, entitled

"Nurses 'perceptions toward nurses-led weaning in an intensive care unit among Palestinians hospitals- qualitative study (focus group)"

Has been given of the application form and ready to participate in the research. I received all information concerning the research orally and in writing, and I am fully aware that my participation in this study is voluntary.

Date: Signature of participants

The undersigned confirms that it provided all the necessary information about the research, has delivered a copy of the above request and consent form.

Date :----- Signature of researcher:-----

PhD Student: Fatima Hirzallah RN, MSc, CNS

E-mails: fatimahirzallah@najah.edu

fatima_herzo@yahoo.com

Phones: +972 599149318/ Palestine, +351 932274636/ Portugal

(Appendix Vb) Informed consent sheet

I'm a teacher at An-Najah National University at faculty of medicine and health sciencesnursing department, PhD candidate at University of Porto/Portugal. I have to write a thesis project as a university requirement overseas. The project describes a scientific study on the **"Impact of nurses-led weaning protocol on outcomes of mechanical ventilation for critically ill patients among Palestinian hospitals"**. your cooperation will be vey appreciated.

Background:

Mechanical ventilation(MV) is a method to mechanically assist or replace spontaneous breathing. Approximately 50% of ICU patients need mechanical ventilation. Weaning is the process of discontinuing mechanical ventilation. The weaning process accounts for approximately 40% of the total duration of mechanical ventilation(Esteban et al., 1994). The basic goal for using weaning protocol is to provide a systematic approach to help patients reduce staying in ICU by reducing the duration of mechanical ventilation and improve patient outcomes. Critical care nurse play a central role in helping ICU patients gradual shift in care focus as disease progresses and in developing weaning plans with patients.

Main objective of this study :

The primary objective of this clinical trial is to determine if a weaning protocol led by critical care nurses reduce duration of mechanical ventilation, a weaning time intensive care unit (ICU) and hospital length of stay (LOS), in critically ill adult patients compared to usual care(non-protocolized) among Palestinian and Portuguese hospitals, and is safe.

Personal data and privacy

All information provided on this occasion will be treated to prevent unauthorized access to it.

Participation in the study is completely voluntary. This means, at any time the participants (ICU nurses) can withdraw from the study without giving a reason and without any negative consequences to them.

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If you need any clarifications, please contact:

Fatima Hirzallah, RN, MSN, CNS

PhD candidate at University of Porto/Portugal

Teacher at An-Najah National University

Faculty of medicine and health sciences- Nursing department

E-mails: fatimahirzallah@najah.edu

fatima_herzo@yahoo.com

Phones: +972 599149318/ Palestine

I have received both written and verbal information about the study and had the opportunity to questions. I am aware that participation in this study is voluntary and that I may at any time and without providing any reason to cancel my participation in the study. And I am aware that which is responsible for the application of this protocol are the legal nurse working in the intensive care unit, with accordance with intensive care physician in each step in the protocol.

I hereby give my consent to participate in the study.

Signature of participants	Date:
Signature of researcher:	Date:

Appendix VI- Study approval

State of Palestine

Ministry of Health - Nablus General Directorate of Education in Health



دولة فلسطين وزارة الصحة- نابلس

الإدارة العامة للتعليم الصحى

Ref.: Date:....

الأخ مدير عام الادارة العامية للمستشفيات المحترم ،،،

تعية واحترام...

الموضوع: تسهيل مهمة إجراء دراسة بحثية الجزء الأول من الدراسة

تماشياً مع سياسة وزارة الصحة المتعلقة بتعزيز التعاون مع الجامعات والمؤسسات الأكاديمية بإتاحة

فرص التدريب أمام الطلبة والخريجين والباحثين في المؤسسات الوطنية وإسهاماً في تنمية قدراتهم.

يرجى تسهيل مهمة الباحثة فاطمة حرز الله - طالبة دكتوراه في جامعة بورتو - البرتغال، في عمل

بحث علمي سريري بعنوان:

"Impact of nurses-led weaning protocol on outcomes of mechanical ventilation for critically ill patients among Palestinian and Portuguese hospitals"

وذلك بالسماح للباحثة باجراء المرحلة الاولى من الدراسة وهي جمع المعلومات وذلك في وحدة العناية

المكثفة في مستشفى رفيديا / ICU، في الفترة من 2016/12/28 وحتى 2017/1/15.

علماً بانه سيتم الالتزام بمعابير البحث العلمي والحفاظ على سرية المعلومات ، وتزويد وزارة الصحة

بنسخة من تقرير البحث

مع الاحتدام...



مدير عام التعليم الصحى

ص.ب. 14 تلفون 09-2333901

P.O .Box: 14 Tel.:09-2333901



State of Palestine

Ministry of Health - Nablus General Directorate of Education in Health

الرقسم: عيدا. إ. ٧٧٧٦ / ٢. ٢. ٢

Ref.: Date:.....

الأخ مدير عام الادارة العامية للمستشفيات المحترم ، ، ،

تحية واحترام...

الموضوع: تسهيل مهمة إجراء دراسة بحثية الجزء الثاني من الدراسة

تماشياً مع سياسة وزارة الصحة المتعلقة بتعزيز التعاون مع الجامعات والمؤسسات الأكاديمية بإتاحة فرص التدريب أمام الطلبة والخريجين والباحثين في المؤسسات الوطنية وإسهاماً في تتمية قدراتهم. يرجى تسهيل مهمة الباحثة فاطمة حرز الله – طالبة دكتوراه في جامعة بورتو – البرتغال، في عمل بحث علمي سريري بعنوان:

"Impact of nurses-led weaning protocol on outcomes of mechanical ventilation for critically ill patients among Palestinian and Portuguese hospitals"

وذلك بالسماح للباحثة باجراء المرحلة الثانية من الدراسة وهي تشكيل فريق وتدريب مجموعتين كل مجموعة مكونة من 8 ممرضين/ات وذلك في وحدة العناية المكثفة في مستشفى رفيديا / ICU، في الفترة من 2017/1/15 وحتى 2017/1/21.

علماً بانه سيتم الالتزام بمعايير البحث العلمي والحفاظ على سرية المعلومات ، وتزويد وزارة الصحة

بنسخة من تقرير البحث

malerall za



ص.ب. 14 تلفون 2333901-09

P.O .Box: 14 Tel.:09-2333901



Ministry of Health - Nablus General Directorate of Education in Health

State of Palestine

Ref.: Date:.....

الرقم: <u>حالم المرام ا</u>

دوية فلسطين

وزارة الصحة- نابلس

الأخ مدير عام الادارة العامة للمستشفيات المحترم ،،، تدية واحترام...

الموضوع: تسهيل مهمة إجراء دراسة بحثية الجزء الثالث من الدراسة

تماشياً مع سياسة وزارة الصحة المتعلقة بتعزيز التعاون مع الجامعات والمؤسسات الأكاديمية بإتاحة فرص التدريب أمام الطلبة والخريجين والباحثين في المؤسسات الوطنية واسهاماً في تنمية قدراتهم. يرجى تسهيل مهمة الباحثة فاطمة حرز الله - طالبة دكتوراه في جامعة بورتو - البرتغال، في عمل بحث علمي سريري بعنوان:

"Impact of Nurses-Led weaning protocol on outcomes of mechanical ventilation for critically ill patients among Palestinian and Portuguese hospitals" وذلك بالسماح للباحثة باجراء المرحلة الثالثة من الدراسة وهي تطبيق البروتوكول وذلك في **وحدة العناية** المكثفة في مستشفى رفيديا / ICU، في الفترة من 2017/2/15 وحتى 2017/3/15. علماً بأن آلية البحث تتضمن أخذ موافقة الطبيب المسؤول عن الحالة في كل خطوة يقوم بها الممرض لتطبيق

بروتوكول الفطام عن جهاز التنفس الصناعي.

علما بانه سيتم الالتزام بمعايير البحث العلمي والحفاظ على سرية المعلومات، وتزويد وزارة الصحة وية فلسطين وزارة ال بنسخة من تقرير البحث.

مع الاحترام...

نسخة: مدير دائرة التمريض والقبالة المحترمة/ جامعة النجاح





ة للت

مدير عام التعليم الصحى

THE IMPACT OF NURSE-LED WEANING PROTOCOL ON THE OUTCOMES OF MECHANICALLY VENTILATED CRITICALLY ILL PATIENTS

FATIMA MOHAMMED HIRZALLAH

INSTITUTO DE CIÊNCIAS BIOMÉDICAS ABEL SALAZAR