INFORMED CONSENT FOR TRAUMA PATIENTS: AN EXPERIMENT TO IMPROVE TAIWANESE PATIENT KNOWLEDGE AND SATISFACTION AFTER INFORMED CONSENT FOR DEBRIDEMENT OF COMPLICATED WOUNDS

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A dissertation submitted to Johns Hopkins University in conformity with the requirements for the degree of Doctor of Public Health

Baltimore, Maryland
November 2015

ABSTRACT

Background: Valid informed consent is an ethical fundamental element and a prerequisite of law and regulation for clinical treatment. Trauma patients with physical pain and emotional stress under an environment of time constraint in emergency settings usually have difficulty in understanding the information presented to them. It is vital that physicians convey any complicated treatment information to patients, and patients need to have adequate knowledge about the treatment to facilitate individual choice.

Aims: The study has three aims. The first aim is to explore what the current state of art for informed consent is, and how we can improve the quality of the informed consent process for trauma patients in the emergency department. The second aim is to develop an audiovisual video containing the information for the informed consent process in trauma patients undergoing the surgery, and to develop and validate a knowledge measure instrument to quantify the understanding of trauma patients for informed consent to surgery. The third aim is to compare the understanding and satisfaction of trauma patients between video and routine informed consent groups.

Methods: To address the first aim, a systematic review is conducted to identify relevant articles. To address the second aim, an audiovisual video including information about the surgical procedure, benefits, risks, and alternatives is developed. One panel of experts is invited to develop the script for the video based upon the consensus from the modified Delphi technique. Furthermore, the development of the knowledge measure instrument is based on the literature and the consensus of experts. To address the third aim, a prospective randomized controlled trial is conducted in the emergency department, and a convenience sample of targeted trauma patients is enrolled.

Findings: From the literature, it is found that trauma patients have poor recall of risks and complications, while written information, pamphlets or video have positive effect on patients' understanding and satisfaction. Modified Delphi technique is a useful method to collect and reach experts' consensus to develop the contents of informed consent. Moreover, the audiovisual video containing information about informed consent to surgery for trauma patients was developed and pilot-tested as well as the knowledge measure instrument for evaluating the understanding of trauma patients. Furthermore, by using the educational video, patients were found to have better information, more understanding and higher satisfaction. The video-assisted method is, accordingly, a good vehicle for improving the informed consent process for trauma patients in the emergency department.

Conclusion: The content of informed consent should be developed by integrating a variety of experts' opinions, especially patients. Using educational videos is a good tool for improving informed consent process for the surgery in trauma patients. Future studies should be conducted to develop a structured and standardized informed consent process and evaluate the effectiveness in combination with healthcare providers, patients, and informed consent experts. Institutions should give top priority to ensure patient-centered health care and improved quality of care for trauma patients.

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ACKNOWLEDGEMENTS

Studying abroad has opened up new horizon of view for me. I would like to express my gratitude to all those who helped me during the program. First, I would like to express my greatest appreciation for Dr. Shi. I have been extremely fortune to have Dr. Shi as my advisor and mentor. He is always supportive of my work. His consistent encouragement and guidance granted me so much confidence to concentrate on my research interests. He has walked me through all the stages of the program. Without his consistent and enlightening instruction, this thesis could not be finished successfully.

I especially acknowledge all my committee members, alternative committee members, the faculty members, and administrators who helped me throughout this process. Professor Pien-Chien Huang, a well-renowned scholar as the chair of the committee, has offered me valuable suggestions and expert guidance. Dr. Jill Marsteller is so nice and supportive, and provides the insightful advice, especially for my proposal and at the final stage of this thesis. Dr. Chiung-Yu Huang is also nice and supportive, discussing with me even on weekend morning, and provides precious opinions for my thesis. Professor Yin-Chun Tien, who is another mentor in Taiwan, always provides his patience and insightful recommendations as well as thoughtful ideas. I would like also to thank Dr. Sydney dy and Dr. Sukon Kanchanaraksa, who provide practical and thoughtful suggestions for my thesis proposal.

I want to thank Mary Sewell, the academic coordinator of our department. Her kind and timely assistance has been so important to me. I also pleased to acknowledge my classmates for their invaluable assistance throughout the program and the preparation of the thesis. Moreover, I would like to thank all my colleagues in Taiwan. Without their support, it is impossible for me to finish the program.

I have been blessed to have a wonderful family. I would like to express my deepest gratitude to my wife, Chia-ju, for her full support. She is always accompanying me, taking care of me, and helping me with love. She allows me to finish my work without worries. She is also a very thoughtful scholar and researcher to discuss with. To my wife: I hope that you know how much I love you. I will never be able to thank you enough for all that you have done for me. To my 8-year-old son, Evan: I am always admiring you full of energy. I should

finally like to express my gratitude to my beloved parents who have always been helping me out of difficulties and supporting me.

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CHAPTER ONE

Introduction

Background

The doctrine of informed consent has been recognized as the fundamental ethical element and legal prerequisite in contemporary medicine for approximately fifty years. It has encouraged patients to become actively engaged in the health decision-making process concerning their treatments.[1-4]

Traumatic injury is the sixth leading cause of death in all patients, and one of the leading causes of death in patients 25-44 years of age in Taiwan.[5] Due to the unique traits of emergency situations, the informed consent in trauma patients is one of the most profound and emotional challenges for patients and their families. As most situations occur in emergency settings under time constraint, emotional stress, and physical pain of sudden injury in patients, patients and their families often have difficulty in absorbing and understanding important information essential to providing their consent.[1, 2, 6] Moreover, in the case of trauma patients having different values and perspectives with physicians toward the treatment, giving their consent may further increase the psychological stress of patients and family members.

Informed consent is more than a process, but is not only a document.[7-10] It is a communication process in which physicians build rapport and relationship with their patients and help patient-centered decision-making. During the traditional consenting process, it has been found that trauma patients have difficulty in retaining the vast amount of information presented to them. Patients are often unable to imagine how the surgery would proceed. Consequently, being unaware of what risks and complications they may confront, patients and their families might not give appropriate consent. Therefore, a cooperative effort by the healthcare providers should present critical information in an effective way, and help patients and family members gain adequate knowledge to make their treatment decisions even under stressful situations.

Audiovisual video presents promising results for educating patients in the emergency settings.[11, 12] However, to our knowledge, using educational video to improve the informed consent process in trauma patients in emergency departments has never been studied.

Study aim

The obtaining of valid consent in trauma patients is essential to ensure adequate information delivery and to maximize patient's rights and interests. The specific aims of this study are:

1) To explore what the current state of art for informed consent is, and how we can improve the quality of the informed consent process for trauma patients in the emergency department.
2) To develop an audiovisual video containing information for the informed consent process in trauma patients, and to develop and validate a knowledge measure instrument to estimate the understanding of trauma patients for informed consent to surgery.
3) To compare the understanding and satisfaction of trauma patients between a video presentation group and a routine informed consent group.

Study significances

The study significances of the study are:

1) The current state-of-art for informed consent for clinical treatment in trauma patients is explored.
2) The content of informed consent is developed by a scientific method by integrating the opinions of different stakeholders, especially patients.
3) The knowledge measure instrument evaluating the understanding of informed consent for trauma patients is developed and validated.
4) For trauma patients and their family members, the audiovisual video may

help them understand information about the treatment, and facilitate medical decision-making.

5) The institution should develop the strategies and structured methods to better inform trauma patients to facilitate decision-making about their treatment, and improve patient satisfaction.
6) For healthcare providers, the information aid may be a useful tool to structure and standardized the informed consent process in order to improve communication between healthcare providers and patients, and facilitate the treatment decision.

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CHAPTER TWO

Principles of Informed Consent

Informed consent, whether consent to treatment or refusal of treatment, has become an ethical foundation and legal prerequisite for medical treatment, and has been deeply embedded in contemporary medicine for approximately fifty years.[1-3] In the law, informed consent requires physicians to disclose information to patients about a treatment course. In ethics, informed consent has the broad view of "encouraging patients to play an active role" in their treatment decisions.[2]

Philosophy

In philosophy, there are two fundamental moral values nurtured by informed consent: patient well-being and patient autonomy.[1, 2]

Patient Well-Being

Since ancient times, the core value of medicine is to protect and promote patient well-being.[2] As Moskop has stated:

"Physicians make important contributions to the overall well-being of their patients, namely, in their efforts to restore and protect health, and to eradicate, ameliorate, and prevent disability, disfigurement, and suffering. Patients rely on the expertise of their physician to identify those treatments that have the potential to benefit them."[2]

He also described this notion as being quite complicated, since different procedures or surgery, the risks, complications, and alternatives may widely differ. Moreover, it also depends on the patient's own goals, preferences, attitude toward quality of life, and values.[2]

"For instance, whether amputation or attempted reconstruction will best serve the well-being of a patient with severe injury of a limb probably will depend on the patient's own attitudes and beliefs regarding disfigurement, physical function, pain, and risk-taking behavior."[2]

Although healthcare providers have the professional knowledge of a treatment,

patients will always know what the best choice for themselves is based on their values and goals. Hence, healthcare providers must dedicate themselves to inform their patients about risks and alternatives in order to help patients make treatment decisions and promote patient well-being. [2]

Patient Autonomy

Moskop describes autonomy as follows:

"Autonomy, understood as the ability to make and to carry out important decisions about one's life, is a second fundamental moral value underlying the doctrine of informed consent. Respecting patient autonomy in the choice of medical treatment can have an important instrumental value; as discussed earlier, it can promote patient well-being."[2]

In addition to its instrumental value to promote patient well-being, "autonomy is recognized as a value in itself, apart from its consequences for well-being."[2] Autonomy means literally "self-rule" and is the principle on which the informed consent doctrine is founded. [4, 5]

Based on the philosophical theory of Immanuel Kant, "Philosophers argue that the unique abilities of human beings to engage in moral reasoning and to make moral choices command our respect for those choices."[2]

"Kant held that persons should be treated as ends in themselves and not as means to some end. Mill extended this to say that the personal freedom of persons could not be violated unless they were a danger to someone else or they did not understand the consequences of their actions on others."[6]

Informed consent protects patient's autonomy. When a patient is competent, he or she has the free will to choose or refuse treatment according to their judgment on the consequences of a treatment. [2]

"Respecting autonomy by securing the patient's informed consent may be

especially important" for patients in the emergency department, same as in trauma patients, because many "patients do not choose their care setting, and most do not choose their care provider."[2]

Fundamental elements for informed consent

Informed consent comprises several important components as the fundamental elements include 1) competence, 2) disclosure, and 3) voluntariness.[2, 7, 8] "It means a substantially autonomous authorization by a capable (competent) individual to whom adequate information has been disclosed and who comprehends that information in terms of the nature, risks, benefits, and alternatives to the procedure."[4]

Competence

A competent individual is meant that one has the "capacity", or "decision-making capacity." The "capacity", or "decision-making capacity," is the ability to understand information relevant to a decision and to appreciate the reasonably foreseeable consequences of a decision or lack of decision."[9] Therefore, if patients have decision-making capacities, they should have the ability of communicating their decision, understanding the information concerning their diseases or conditions, appreciating the consequences of the choice, and balancing the risks and benefits about their decisions.

In practice, in most situations, physicians evaluate and determine patient's capacity and decide when to seek substituted decision maker.[10] There should be a structured approach and standard to evaluate patient's decision-making capacity. However, there is no clear standard to evaluate patient's capacity in clinical practice so far, neither are there formal practice guidelines.[10] When patients are in acute or chronic conditions such as neurologic disorders or cognitive impairments among older patients, there might be some influence on their decision-making capacity. Physicians

have to know the patient's decision-making capacity clearly, or seek help when in doubt, such as psychiatric consultation. If it is difficult to determine the patient's capacity, physicians have to consider deferring the treatment option until the question of decision-making capacity has been resolved unless urgent.[10]

If patients have no decision-making capacities in an emergency condition, physicians have to provide appropriate treatments under the principle in which a reasonable person may decide to consent to, or seek consent from a surrogate decision-maker or family members [10] If a patient has advance directives, physicians should respect these such as the patient's choice.

Disclosure

Disclosure refers to "the process during which physicians provide information about a proposed medical investigation or treatment to the patient."[11] Physicians should inform patients about the benefits, potential risks, alternatives, and possible consequences for a proposed treatment options, and respect for patients' autonomous choice based upon the value and believes of patients themselves. A signed consent form cannot replace the importance of the informed process. During the process of information interchange, the physicians and patients can share the perspectives and values for each other and build the trust in the patient-physician relationship.[11]

How much information is sufficient, remains controversial. Without information, patients are not able to make their decision and provide their consent to treatment. Too much information provided to patients creates the same problem just as too little.[5] Therefore, how to provide the amount of appropriate information that the patient would like to know remains a challenge. The physician has to consider each patient's individual condition and special needs to provide such necessary information for the patient.

There are two standards for the disclosure of information in health care. The first

standard is “the professional standard”.[2, 5, 12] It is the duty for healthcare providers to “disclose all information that a reasonable practitioner would provide.”[13] The second standard is “the reasonable patient standard”.[2, 5, 12] Based on this standard, the healthcare providers have to provide all the information that a “reasonable” person would like to know when making a treatment decision.[2] Therefore, physicians should communicate with patients about all the information of the treatment to the extent that a reasonable practitioner will provide and a reasonable person might want to know.

Furthermore, patients have to understand what information physicians provide to them to make an autonomous decision. Many conditions may have an influence on patient’s understanding, such as illness, irrationality, and immaturity.[5] Many medical terms may possibly confuse patient’s understanding. Sometimes, the same word may mean something different to physicians and patients. Therefore, physicians must try their best to use those words that patients can understand and consider the patient’s medical condition to ensure their best understanding.

Voluntariness

Eventually, the patient must be allowed to make the decision freely, without any coercion or duress.[8] Voluntariness refers to “a patient’s right to make treatment decisions and decisions about his or her personal information free of any undue influence.”[11] It is not acceptable for patients to be forced to make any medical decision or accept treatment. Some external factors interfering with such voluntariness include “the ability of others to exert control over a patient by force, coercion, or manipulation.” “Coercion may involve the use of threats, explicit or implicit, to make the treatment accepted.”[14] “Manipulation involves the deliberate distortion or omission of information in an attempt to induce the patient to accept a treatment or make a certain decision”[14]

Though voluntariness must be emphasized, it is not to imply that the persuasion cannot be attempted by physicians.[14] Physicians are not prohibited to provide suggestions or advice of a treatment option for the patient. Physicians may provide suggestion or advice of a specific treatment option based on clinical evidence or personal experience in view of the patient's values and perspective. Patients should have the free will to accept or decline that suggestion on their own. Physicians must be aware of "the fine line between persuasion and coercion: the duty to provide sufficient information and advice to support a patient's autonomous decision making, contrasted against allowing a patient's actions to be substantially controlled by others."[14]

Consent

Consent usually implies that a patient accept a proposed treatment or procedure, but also means a patient may choose an alternative treatment or refuse to accept the treatment in the broad concept of consent.[11] Several authors have suggested that "the process of obtaining consent can be the most important component of a successful physician-patient relationship."[11]

Except for the ethical elements for informed consent, the law has requirements for informed consent. Based on the law requirements, the physician should provide explanations of the procedure, the possible risks and complications, the benefits after the procedure, and available alternatives for the procedure, including the consequences without treatment.[2, 13] Although there is no universal rule as to when and what procedure to consent and document, the written consent form is usually prepared for most invasive procedures with relatively higher risks in clinical practice. [11, 15] If there is no consent document for a specific procedure, physicians may usually write notes for possible risks on the chart.

Kondziolka et al also addresses important points during the informed

discussion for the surgery. Those are “(1) results of pertinent diagnostic studies; (2) probable outcome of surgery; (3) likely benefits of surgery; (4) explanation of what surgery will entail; (5) probable complications; (6) temporary complications, such as postoperative pain and infections, along with treatment for these temporary conditions; (7) permanent results and complications, such as nerve palsies, paresis, plegia, and scars; (8) other risks that are reasonably foreseeable, such as injury to surrounding nervous structures and their sequelae; and (9) reasonable alternatives to the procedure, along with the risks and benefits of the alternatives.”[13]

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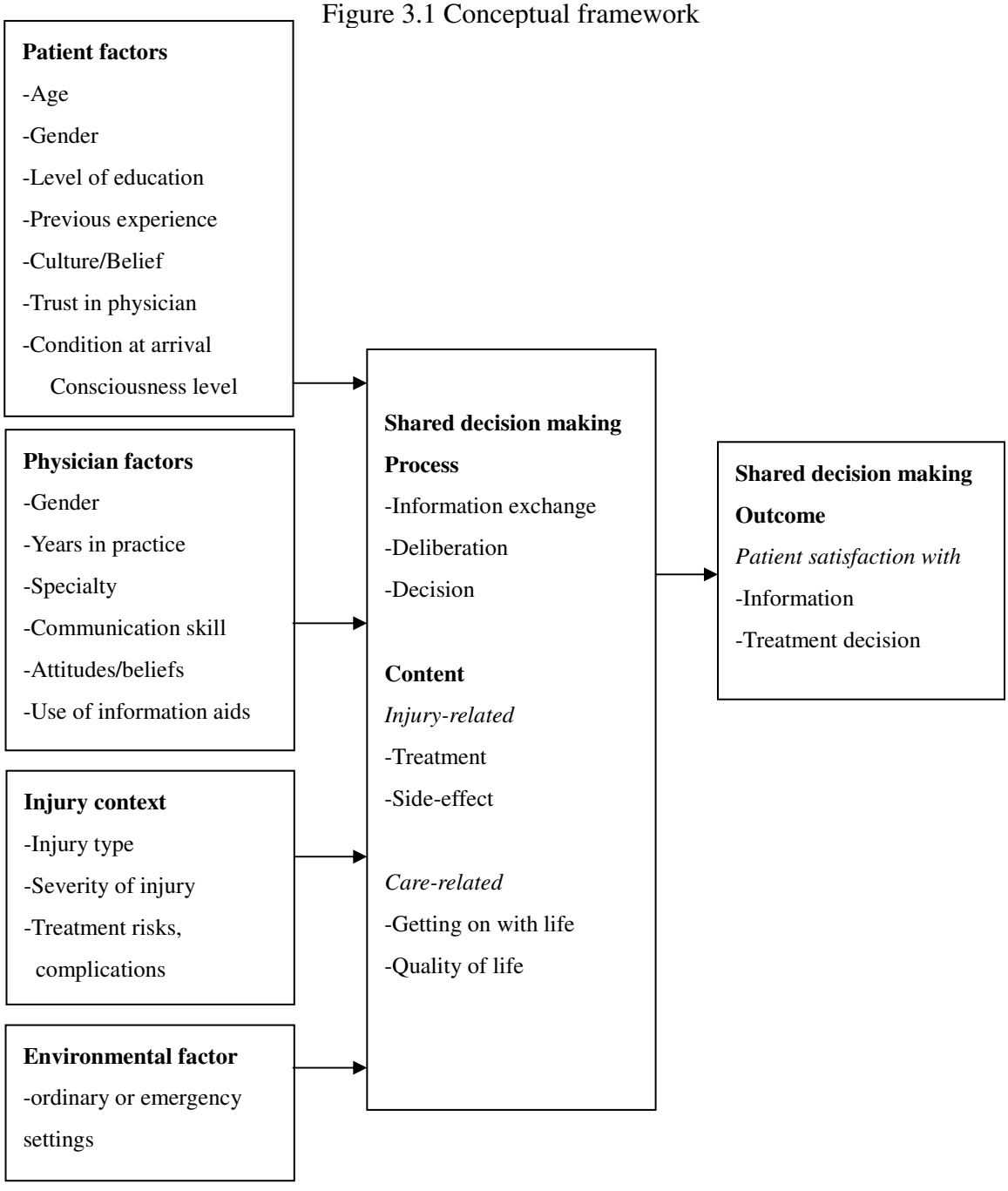
CHAPTER THREE

Study Design

Conceptual Framework

The conceptual framework of our work captures the complex realities of the valid informed consent. The shared decision-making model developed by Leon-Carlyle et al [1] for surgical consultation has been modified and applied to the conceptual framework of this study (Figure 3.1). Patient factors, physician factors, injury context, and environmental factor affecting information exchange, patient's deliberation and voluntarism to making treatment decision and providing consent have been measured. They also have an impact on the satisfaction with the information and treatment decision.

Figure 3.1 Conceptual framework



Study Aims, Research Questions, and Hypothesis

This study has three aims.

Aim 1: To explore what the current state of art for informed consent is, and how we can improve the quality of the informed consent process for trauma patients in the emergency department.

Research questions 1: What is the current state of art for informed consent, and how can we improve the quality of the informed consent procedure for trauma patients in the emergency department?

Hypothesis 1: based on the literature, I hypothesize that using an audiovisual video or multimedia presentation can structure and standardize the informed consent process by providing the essential information, including the surgical procedure, risks, benefits, and alternatives for trauma patients so that they might make a treatment decision based on the current state of art for informed consent, and can improve the quality of the informed consent procedure for trauma patients in the emergency department.

Aim 2: To develop audiovisual video containing information for the informed consent process in trauma patients undergoing the surgery of debridement, and to validate a knowledge measure instrument to measure the understanding of trauma patients for informed consent to debridement.

Question 2: What is the essential information needed for trauma patients to make a treatment decision during informed consent for the surgery of debridement? And are the knowledge measure instruments able to adequately measure the understanding of trauma patients for informed consent?

Hypothesis 2: based on the literature and the requirement of law, I hypothesize that by using the modified Delphi technique, the developed audiovisual video could

contain the essential information, including the surgical procedure, risks, benefits, and alternatives for trauma patients undergoing the surgery of debridement to make a treatment decision, and the knowledge measure instrument will have good validity and reliability to measure the understanding of trauma patients for informed consent to debridement.

Aim 3: To compare the understanding and satisfaction of trauma patients undergoing the surgery of debridement between the video group and the routine informed consent group.

Question 3: Is the video-assisted informed consent better for informing trauma patients about the surgery of debridement?

Hypothesis 3: I hypothesize that trauma patients will have better understanding and higher satisfaction when using the video-assisted method to deliver the information.

Overview of Methods

Definition of trauma and surgery

Trauma

Trauma or injury has been defined as “damage to the body caused by an exchange with environmental energy that is beyond the body’s resilience.”[2] According to Wikipedia, trauma refers to “in physical medicine, trauma (injury) is damage to a biological organism caused by physical harm from an external source. The term is sometimes used to refer to trauma centers and other medical units that deal with trauma. Major trauma is injury that can potentially lead to serious outcomes.”[3]

Namely, trauma involves a sudden physical injury that results in a body wound or shock, and the mechanism might be accident or violence. The American Trauma Society defines trauma as an injury caused by a physical force. More often, trauma may result from motor vehicle collisions, blunt injuries, falls, gunshots, fires and burns, stabbings, or violence assaults, etc. According to the American College of Surgeons Committee on Trauma, trauma refers to a body injury that may include a large range of severity.[4]

In this study, trauma patients are defined as the patients have physical harm and medical attention is needed.

Surgery

As Thompson described: “Surgery is defined in the Oxford English Dictionary as: The art or practice of treating injuries, deformities and other disorders by manual operation or instrumental appliances.”[5]

According to the definition of “surgery” from American College of Surgeons Statement ST-11[6]:

“Surgery is performed for the purpose of structurally altering the human body

by incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing, radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel."

In this study, the specific surgical procedure requiring consent is the debridement, which is a process of cleaning a wound, removing nonviable material, all foreign matter, and poorly healing tissue, with a view toward preventing infection as well as improving wound healing.[7]

Study design and data collection

Systematic review

The first part of the study conducted a systematic review to identify relevant articles. The search term "informed consent [ti]" was applied to Pubmed (1979-2015). The inclusion criteria of search studies included full-text original articles with experimental or observational study design in adult trauma patients requiring consent for any surgical procedure and published with peer-reviewed process in scholarly English journals. All studies had to have an outcome or

satisfaction evaluation. In addition, the references of the selected articles were searched by hand and reviewed. Studies conducted for informed consent in clinical or research trials were excluded.

For non-randomized studies, the methodological quality was assessed using the framework from the Newcastle-Ottawa Quality Assessment Scale.[8, 9] For randomized controlled trials, the methodological quality was assessed using the framework for assessing the risk of bias developed by the Cochrane Collaboration.[10, 11] The narrative approach was performed to synthesize the results.

Development of educational video

The second part of the study focused on developing the educational video. The information on the informed consent documents in our hospital is usually simplistic and not validated. Besides, there is no developed specific informed consent document for surgical debridement of complicated limb wounds in our hospital. Therefore, we developed a video specific to the surgery of debridement for complicated limb wounds. The content was developed using the modified Delphi technique. A panel of experts from different fields with a variety of expertise, including trauma surgeons, nurses, informed consent experts, lawyer, patients, was invited to participate. Each expert was chosen by recommended by two specialists from Kaohsiung Medical University Health Care System. The Kaohsiung Medical University Health Care System includes one tertiary medical center with more than one thousand and six hundred beds, and two metropolitan hospitals with more than eight hundred beds in total. The patients were recommended by nurse practitioners working in the plastic surgery ward. The modified Delphi technique was applied to collect the experts' opinions that might contribute to development of the video. The results from the experts were finalized and the script revised for the video. The content of the video

contained the information that patients would want to know and be under the ethical principles and regulations of the law. After the script was confirmed, a multimedia company was contracted to develop the video.

The knowledge measure instrument

The knowledge measure instrument was developed the same time as the video development. The questions measuring the patient knowledge about the informed consent included the essential information that trauma patients might need and in which the consensus of the experts might reach. Each question was equally weighted, and in written form with multiple-choice format. The instrument was administered in the pilot test of the study. The questions were further eliminated if the correction rate had no statistical significance in the pilot test.

Intervention

The third part of the study was to conduct a prospective randomized controlled trial. Patients were enrolled on a sample of adult trauma patients scheduled to receive the surgery of debridement for complicated wounds over limbs in the emergency department of Kaohsiung Medical University Hospital. Wounds over face were excluded because of cosmetic concern. Wounds involving tendon rupture or nerve injury were also excluded because of different rehabilitation programs postoperatively. Patients who were randomized to the intervention group watched a video illustrating the surgical procedure and its benefits, risks, and alternatives after the physician-patient discussion. The control group underwent routine discussion, receiving information for the surgery of debridement from their physician and written consent form. Before and after their informed consent process, all participants were asked to complete a knowledge measure. Questions using the 5-point Likert scale were asked to evaluate their satisfaction with the informed consent process after the educational sessions.

Data analysis

Sample size determination

To achieve the third aim, sample size was determined a priori according to several parameters. A careful literature review did not reveal previous studies similar to this research in target population or an instrument designed to measure the areas of interest in this study. The majority of previous research on improving informed consent process for patients used available sample populations, and did not perform public power analyses.

Accordingly, the following assumptions were made regarding the power analysis for this study: (a) the intervention boosts the mean score on the measurement instrument from a low beginning to a higher end point (mean difference by 10%); (b) the scores are normally distributed; (c) the standard deviation is 18 for the control group and 16 for the intervention group; (d) the level of significance is 0.05 ($p<0.05$); (e) a two-tailed *t*-test; (f) assuming a 10% dropout rate is used to analyze the data. Given these assumptions, it was determined that a sample size of 68 in each group was needed to achieve an effect size more than 0.5 with 90% power and a significance of 0.05.

Data process and statistical analysis

Descriptive statistics were used to analyze the baseline characteristics of the control and intervention groups. Mean and standard deviations were calculated for continuous variables if they were normally distributed, and proportions were calculated for categorical variables. The difference of experts' rating for each item during the modified Delphi rounds was compared using Wilcoxon signed-rank test. The exact McNemar's test was used to compare the correction rate of knowledge test for each question before and after video education. Mean scores on the change of knowledge measure and patient satisfaction were compared using Student's *t*-test

between each group. Changes in participation between before and after educational knowledge were compared using paired *t*-test within each group. Categorical variables were analyzed by Chi-square test, or two tailed Fisher exact test. Independent factors found to be associated with the difference of knowledge score and patient satisfaction by univariate analysis were subsequently entered into multivariable regression models.

Stata version 10.0 (StataCorp, College Station, TX) was used to analyze all statistical data.

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CHAPTER FOUR

Manuscript One

Informed consent in trauma patients: a systematic review

Abstract

Background

Obtaining adequate informed consent in trauma patients is a challenging and time-consuming process. Because of the unique nature of trauma care, informed consent is the only way to respect patients' autonomy. Healthcare providers have to communicate complicated medical information with patients to help them make an informed decision. The study aim is to explore what the current state of art for informed consent is, and how we can improve the quality of the informed consent process for trauma patients in the emergency department.

Methods

The systematic review was conducted to identify relevant English full-text original articles with experimental or observational study design in adult trauma patients from Pubmed (1961-2015). Studies conducted for informed consent in clinical or research trials were excluded. The reviewers reviewed titles and abstracts of searched articles and extracted relevant data using the structured form. The narrative approach was performed to synthesize the results.

Results

A total of 5762 articles were identified at the initial search. Only four studies were included in the review for narrative synthesis. All studies were conducted for orthopedic surgeries. No study was notified to be conducted in the emergency department. Risk recall and comprehension were increased when written or video information was provided rather than when information was only provided verbally; satisfaction was also improved when patients received written and verbal information rather than receiving verbal information only.

Conclusions

There is a vast amount of articles published in the field of informed consent, but very few of these have focused on the population of trauma patients. No empirical evidence has supported the success of informed consent for trauma patients in the emergency department, especially within the necessarily very limited time frame. Future studies should be conducted to develop a structured and standardized informed consent process and evaluate the effectiveness. Institutions should give top priority to ensure patient-centered health care and improved quality of care for trauma patients.

Background

For fifty years, the doctrine of informed consent, as the fundamental ethical element and legal prerequisite in contemporary medicine, has encouraged patients to become actively engaged in their own health decision-making process. [1-4]

Traumatic injury under emergency situations is the sixth leading cause of death in all patients, and one of the leading causes of death in patients 25-44 years of age in Taiwan[5], presenting the informed consent dilemma as a most profound challenge for patients and their families. Time constraints, emotional stress, and physical pain of sudden injury in patients mitigate immediate absorption and understanding of relevant information essential to providing consent.[1, 2, 6] Patient values and perspectives at variance with those of physicians toward treatment might further increase the psychological stress of patients and family members.

Informed consent ideally is a process were physicians build rapport and relationship with their patients and assist them in decision-making.[7] Trauma patients have been found to have difficulty in retaining information presented to them, and are therefore unable to imagine the surgery process. Consequently, patients and their families might not give appropriate consent. Any cooperative effort by healthcare providers should present critical information effectively and assist patients and family members make logically clear treatment decisions, even under stressful situations.

Challenges of obtaining informed consent in trauma patients

This part proposes challenges of the informed consent in trauma patients. Issues will be discussed including the involuntary nature of emergency care for trauma patients, consent in medical emergency for trauma patients, and consent for incompetent patients.

Some authors have found that recall about the consent process during acute illness of patients is variable and sometimes poor, where many patients have no

recollection about the process at all.[8, 9] It is especially true that the poor recall in trauma patients who have potentially serious complications and have little time to absorb complicated information needs to be addressed in order to improve the consent process and increase its validity.[9] Therefore, a cooperative effort by healthcare providers should present critical information in an effective way, and help patients and family members gain adequate knowledge to make their treatment decision even under stressful situations.

Involuntary nature of emergency care for trauma patients

Informed consent is an important concept in the emergency settings. The core value of informed consent must be based on patient autonomy and consent given voluntarily. However, in many situations, the patients may not be voluntarily making the treatment decision.[10] Unconscious trauma victims, taken by the ambulance to the emergency department, have no opportunity to choose the treatment team to treat them.[10] Moreover, there are many institutions mainly designed and functioning for the general public and not for individuals, which may limit patient autonomy and decision-making. [10]

Moreover, in many emergency circumstances, the patient may be meeting the physician for the first time; a good patient-physician relationship may not be built, and the physicians might not know the values and preferences of the patient. “A primary care physician who has had a long ongoing relationship with a patient may already have a good understanding of the patient’s values and goals and be able to use that understanding in formulating treatment alternatives.”[10] Similarly, physicians might know little about trauma patients’ values and preferences; it may only depend on the patient’s self-expression about their values and preference to make a treatment decision.[10]

Therefore, in trauma patients, there is often an unavoidable coercive element

where the patients may not have the chance to choose the hospital and physicians, and the priority for both hospital and physician may not meet individual needs. These reasons may explain the involuntary nature of emergency care, [10] the same with trauma patients, and the patients might not act voluntarily for consent procedure.

Consent in medical emergency for trauma patients

Though obtaining informed consent for medical treatment is important, it has to be admitted that it is not necessary to obtain consent from patients for medical treatment in any and all circumstances.[1] There are several conditions where the exception to informed consent for medical treatment is permitted. When patients in an medical emergency need immediate treatment to save their lives or avoid serious harm and patients lack the capacity (competence) to give consent, these are common conditions where exception for consent is permissible.[1] Moreover, other conditions where informed consent might not be required include “patient waiver of consent”, in “public health requirements”, and “therapeutic privilege”.[1, 2, 11, 12]

According to the exceptions, informed consent need not be achieved in medical emergencies, “when immediate intervention is necessary to prevent death or serious harm to the patient.”[13, 14] Some physicians might misinterpret informed consent as not being important based on the exception when patients present to emergency settings. However, most patients in emergency settings, including trauma patients, might not be in a state of medical emergency, and are competent to give consent.[2, 15, 16] When a physician in the emergency setting encounters a patient, the physician has to determine whether there is sufficient time to obtain informed consent without delaying the treatment and risking the patient.[17] Therefore, in most trauma patients who will receive surgery in an urgent situation, physicians may have time to educate patient and their families, and have the obligation to obtain a valid consent from patients.

Nevertheless, many issues still remain debated. For example, according to the statement recommended by the American Medical Association, the medical emergency is a situation in which "harm from failure to treat is imminent".[13, 18, 19] However, there is no given clear definition concerning what level of harm is imminent. The physicians may have difficulty and must be dedicated in judging the situation whether informed consent is or is not achieved.

Consent for incompetent patients

When patients are severely injured, such as being in shock or sustaining brain injuries, patients may not have the ability to participate in the discussion for their treatment decision and to provide consent. When patients do not have the capacity to provide consent, the physicians have to consider and make medical decision based on the patient's "best interest",[20] or seek consent from patient surrogates. "Surrogate decision-makers are called upon to make decisions on behalf of incompetent patients."[21, 22]

There are special challenges for physicians to obtain a valid informed consent and for surrogates to make treatment decisions on behalf of the patient's best interest for emergency surgery in incompetent trauma patients. Surrogates usually have to make the treatment decision in a short period of time. If the patients are transferred to a remote hospital far away from their families or surrogates, the process for seeking consent from surrogates may be a challenge for physicians and hospitals. Even surrogates have found that it remains a challenge if surrogates are unable to arrive in a timely manner to provide consent, and discussion for treatment decision between physician and surrogate might be limited. The quality of communication may be insufficient.

Strategies of improving consent process in the emergency settings

Although informed consent is an essential issue for physicians, it has been

questioned to the extent that “most physicians do not devote appropriate importance to it in their daily duties”.[23] Some authors have also reported a similar concern in Japan. Physicians may just try to obtain a consent signature without the deep understanding of the fundamental ethical principles of informed consent.[24] One study reported that, in South Africa, doctors might have the general concept and knowledge; however, the practicing of the informed consent process was still inadequate.[25] Furthermore, one study had revealed that the administration and documentation of the informed consent for surgical health care at university teaching hospitals is inadequate.[26] In our clinical experience, especially in the emergency department, informed consent is usually obtained by residents or chief residents for most procedures or surgeries. The residents may not have much clinical experience in expecting many unforeseen treatment complications and risks. Furthermore, some residents may not have good communication skills to explain the information in detail. The quality of information delivered to patients may not be complete. Hence, patients’ needs may not be properly met by current principles for consent to treatment, particularly in emergency circumstances.

Although in many hospitals, there are written informed consent forms with the explanation of the procedure, risks, alternatives in detail, it should not be presumed that each patient can always understand all the information given to them concerning their case. Moreover, it might be said that such written consent is generally designed for the protection of clinicians and hospitals from litigation rather than for the benefit for the patients.[23, 27] This is not concordant with the core values and principles of informed consent, and is possibly harmful to the patient-physician relationship. Therefore, physicians and institutions should develop strategies to improve the informed consent process in the best interests of patients.

As Bernat and Peterson have reported, “all surgeons should conceptualize consent not as a discrete event but as an ongoing bidirectional process of communication, education, question-answering, and listening with the patient or surrogate that proceeds through the continuum of care.”[28] In shared decision-making, the physician serves as a partner of the patient. The physicians provide the patients with professional knowledge about diagnosis, treatment options, prognosis, with possible risks and benefits, and frequently may propose treatment recommendations, and patients may provide physicians with their own values, goals of life, and preferences of treatment to help physicians recommend a proper decision. [28]

As just mentioned, informed consent should be regarded as a continuing conversation and discussion between patient and physician throughout the patient’s care.[12, 28-30] Patients may change their mind for the treatment decision anytime based on the patient’s condition and the information they may receive. Thus, “informed consent is also viewed as a process of patient-centered decision-making.”[28]

Innovative ways to improve information delivery

Many strategies including use of illustrative materials, leaflet and pamphlets, video description, and interactive computer programs,[31-47] and “repeat back” strategy have been adopted to bring about better patient understanding [48, 49], but such strategies have revealed both advantages and limitations.

“Most patients have a positive attitude toward receiving information.”[50] However, to what level necessary information becomes “sufficient” is an important determinant of patient satisfaction, and more attention should be focused on this area.[51] Written materials have been shown to increase patient knowledge as a useful tool for patients.[50, 52] Such information as an informational brochure has been

shown to increase patient knowledge of the prognosis [32]; however, such material usually requires active collaboration and compliance on the part of the patient, and transfer of knowledge concerning procedures and risks to the patient is often limited. Some studies indicate a significant number of patients do not even read the consent form before signing [53], while one study concluded that trauma patients often need repeated verbal explanations of the procedure and its potential complications rather than just providing them with written information.[9]

Using video or multimedia modalities to educate patients and assist the informed consent seems to produce satisfactory results. Cornoiu et al reported that using multi-media education to assist the informed consent for knee arthroscopy revealed better understanding. The correct response for patients in the multimedia group was 98%, in comparison with 88% in the verbal group and 76% in the pamphlet group.[54] Several studies have also shown that using a video-assisted method to educate patients resulted in better patient satisfaction and improved patient knowledge of the procedures and risks. [43-45, 50, 52, 55-57]

As most of these studies focused on elective procedures or surgeries, and since the problem of patient understanding and information retention should be greater in emergency settings than ordinary settings, institutions should develop effective educational tools to foster the informed consent process. Delivering such information is also fundamental as is the provision of supportive materials [58]; therefore, it is also crucial to standardize the communication process for patients and their families, and in so doing , make the communication process more effective and efficient. Using such information aids mentioned should reduce the burden of communication between physicians and patients, and secure the consent process by delivering standardized information.

The weight and size of modern electronic tools have previously limited

application in emergency settings, but recent advances in portable and tablet computer technology provide good opportunities for improving patient education for surgery.[6] Innovative, less bulky portable computers have larger screen displays, larger memory storage, and good image resolution, and more easily deliver educational information and videos with good quality of presentations. The use of such innovative computer technology may help preoperative education in trauma patients requiring emergency surgery.

Such technological tools, however, should never take the place of interaction between the physician and the patient, and patients should be given an opportunity to ask questions and voice their concerns.

Therefore, the importance of the effectiveness and efficiency of preoperative education and communication process as well as the entire consent process during emergency surgery should never be underestimated. A good consent process will dramatically increase the satisfaction of trauma patients during emergency surgery; hence, to obtain informed consent effectively and efficiently, a comprehensive tool and a standardized consent process should be developed in emergency settings for trauma patients and their families.

In sum, obtaining adequate informed consent in the emergency department is a challenging and time-consuming process. Because of the involuntary nature of emergency care, informed consent is the only way to respect patients' autonomy.[2, 10] Providers have to communicate complicated medical information with patients to help them make an informed decision. As most situations occurred in emergency settings, the time constraint and the stress as well as the distress by pain or other acute symptoms in patients, the patients and their families often have difficulty in understanding the significant information needed to provide a valid informed consent.[1, 2, 6, 17, 59-63]

On one hand, during the traditional consenting process, it has been found that trauma patients tend to have difficulty in retaining the vast load of information presented to them. On the other, patients often could not imagine how the surgery would proceed. Therefore, using video to assist the informed consent process for the surgery may offer a practical solution. The use of a video to support a preoperative education and interview may improve both patient satisfaction and understanding of information.[55]

Therefore, the investigator would like to address this issue with the addition of a video-assisted informed consent process. To our knowledge, using educational video to improve the informed consent process in trauma patients in emergency departments has never been studied.

Study objective

This study aimed to explore what the current state of art for informed consent is, and how we can improve the quality of the informed consent process for trauma patients in the emergency department. The investigator would like to conduct a systematic review for the informed consent process in trauma patients and intend to answer the above questions.

Methods

Search strategy

A systematic review was conducted to identify relevant articles and the guidelines of PRISMA were abided to.[64, 65] A 27-item checklist and four-phase flow diagram were included in the PRISMA statements. The search term “informed consent [ti]” was applied for Pubmed (1979-2015). The inclusion criteria of search studies included full-text original articles with experimental or observational study design in adult trauma patients requiring consent for any surgical procedure and published with peer-reviewed process in scholarly English journals. All studies had to have the outcome or satisfaction evaluation. In addition, the references of the selected articles were searched by hand and reviewed. Studies conducted for informed consent in clinical or research trial were excluded.

Study data extraction

Two reviewers reviewed titles and abstracts of searched articles. For those studies meeting the interest of this study, the full-text version was obtained and further review was conducted. Two reviewers examined every full-text article using the selection form. If there was a doubt, two reviewers discussed the issue further and reached a consensus. If a consensus was unable to be made, a third reviewer would be consulted.

Two reviewers used the structured extraction form to extract relevant data, including authors, country, study aim, study design, inclusion criteria, participant recruited procedures, numbers of participants, participant characteristics (diagnosis, gender, age, level of education, disease or injury severity, and received surgeries), etc.

Methodological quality assessment

The methodological quality of included articles was assessed. For non-randomized studies, the methodological quality was assessed using the

framework from the Newcastle-Ottawa Quality Assessment Scale.[66, 67] Five domains were modified to assess the risks of bias, including case definition, representativeness of the cases, ascertainment of exposure, same method of ascertainment, and non-response rate. For randomized controlled trials, the methodological quality was assessed using the framework for assessing the risk of bias developed by the Cochrane Collaboration.[68, 69] Six domains were modified in the assessment, including sequence generation, allocation sequence concealment, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other potential treats to validity.

Data synthesis

Because of the heterogeneity of methodology, it was impossible to conduct a meta-analysis, so the narrative approach was performed to synthesize the results.

Results

Figure 4.1 presents the search process in detail to identify the eligible studies for inclusion in the review. A total of 5762 articles were identified at the initial search. 576 articles not published in English and 404 review articles were excluded. 4763 articles not meeting the interest of the study and 14 articles focusing on clinical or research trials were also excluded.

In relation to informed consent for adult trauma patients, only four studies were included in the review for narrative synthesis.[70-73] (Table 4.1) One study was conducted in the United States,[70] one in Turkey [71], and two in the United Kingdom.[72, 73] All studies were conducted for the informed consent process in adult trauma patients. All studies were conducted for orthopedic surgeries. No study was notified to be conducted in the emergency department.

Two study were conducted using an observational study design,[71, 72] and the other two studies were conducted using the experimental study design.[70, 73] The number of the patients involved was 48, 81, 142, and 121 respectively. Three studies provided verbal and written/leaflet information to patients,[71-73] and one study provided verbal and video information to patients.[70] The timing of evaluation for patients was immediately after receiving information and an average of 10 weeks later,[70] first post-operative day,[72] post-operative 1-3 days,[71] and 1-17 days (mean 3.2 days) respectively.[73] Three studies used a questionnaire[70, 72, 73] and one used interview and questionnaire [71] as the method of evaluation. One developed a multiple choice questionnaire to evaluate the understanding of trauma patients about the surgery,[70] and the other three asked the patients to recall the name of the procedure, risks or complications for the surgery.[71-73]

The results revealed that the poor recall of complications was identified for trauma patients than for those patients receiving elective surgery. The risk recall and comprehension were increased when written or video information was provided than when information was only provided verbally. Satisfaction was also improved when patients received written and verbal information than for when patients received

verbal information only.

The assessment of methodological quality

The assessment of methodological quality is presented in Table 4.2. For two non-randomized studies,[71, 72] both adequately described the definition of case, exposure, using the same method for both groups, and reported the non-response rate; however, both studies had the concern of the risks of bias because the selected participants may not represent the population. For randomized controlled studies,[70, 73] both adequately described the incomplete outcome data, selective outcome reporting, and other potential threats to validity. One study did not describe the sequence generation and allocation sequence concealment,[70] while another study did not report the allocation sequence concealment and blinding of outcome assessment.[73]

Discussion

Main findings

A systematic review was conducted to evaluate the informed consent process for trauma patients. The investigators collected four studies for analysis, and found that trauma patients had poor recall of risks and complications, while written information, pamphlet or video had positive effect on patients' understanding and satisfaction. The investigators posit that video or interactive media would further improve patients' comprehension and satisfaction.

Implication for future researches

Informed consent in trauma patients is very important but rarely studied in this field. Further studies for informed consent process in trauma patients in detail have been recommended. More research is needed to support the effectiveness of different information delivery methods on informed consent in trauma patients, and the most effective strategy for the process is necessary to be developed and established.

Furthermore, how to provide adequate education and train healthcare providers to deliver structured and comprehensive information to trauma patients in a very timely manner as well as, at the same time, establish a good patient-physician relationship and build trust are also important issues worth further exploring.

Moreover, informed consent might be waived when the patients are in medical emergency. Further research is needed in exploring how many unconscious trauma patients undergo emergency surgeries without informed consent or surrogate consent, and how the healthcare providers define such medical emergencies. More research is needed for the relationship between patients' outcome and their decision-making.

Implication for policy and practice

The review revealed that research on informed consent for trauma patients is rare. It includes how to use what kind of adequate tool to convey all the information of

possible risks and treatments to deliver to them. It might greatly limit patients' ability to obtain sufficient information concerning the risks and benefits to make an autonomous decision that might respect their own values and really benefit them. We recommend an appropriate information aid should be provided to avoid healthcare providers only giving verbal information with imprecise risks or possibility of outcome (such as low, uncommon, etc). Patients might overestimate or underestimate the possible harm.

Computerized and interactive programs might provide patients with tailor-made and individualized information to help patients comprehend all the necessary information in a very short time frame. We believe that information aids might have many advantages for trauma patients. Especially, the model of shared decision-making has been estimated nowadays. In particular, when there are two or more options for one condition with different risks and benefits respectively, there is no best treatment and professional consensus is not yet achieved. For instance, the options for the treatment of splenic laceration include surgical treatment (splenectomy or splenorrhaphy) and non-surgical treatment (conservative or transarterial embolization). Each option has its own risks and benefits. In some conditions, the healthcare providers might have to discuss these options with patients to obtain their final decision.

Our study has several strengths. The search strategy is comprehensive. As far as we know, no other review study focuses on this topic. Our review also has several limitations. The searched articles are quite rare, and meta-analysis and quantitative analysis are not possible because of the heterogeneity of data. Because the articles are rare and the study samples are relatively small, publication bias might be possible. The results reveal a positive effect, but there might be possible negative effect for unpublished articles.

Conclusions

There is a vast amount of articles published in the field of informed consent, but only a few have focused on the population of trauma patients. No empirical evidence has supported the success of informed consent for trauma patients in the emergency department, especially within the very limited time frame. Future studies should be conducted to develop a structured and standardized informed consent process and evaluate the effectiveness in combination with healthcare providers, patients, and informed consent experts. Institutions should give top priority to ensure patient-centered health care and improved quality of care for trauma patients.

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Figure 4.1 Flow chart for reviewed articles

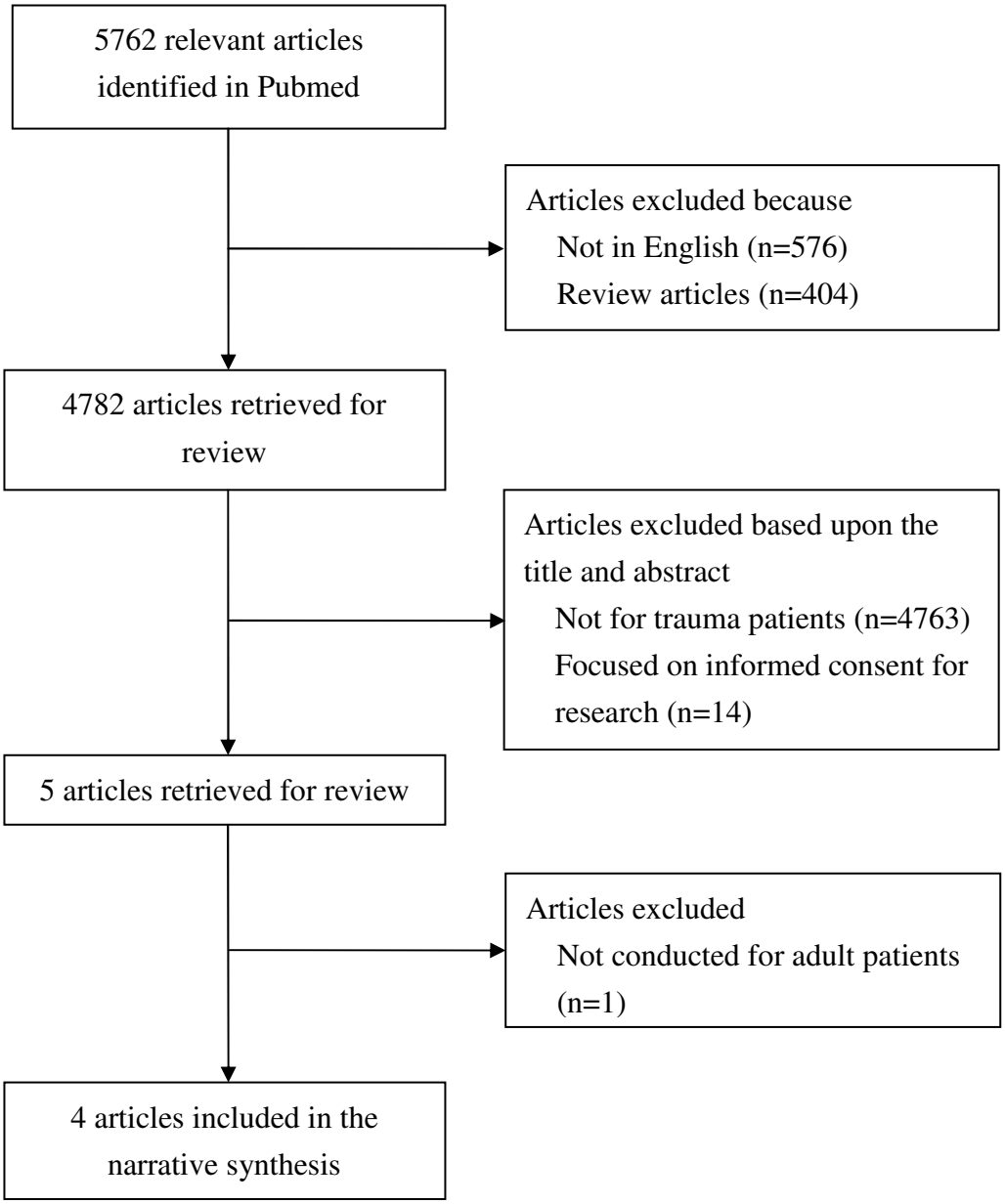

Table 4.1 Selected studies regarding the informed consent process for trauma patients undergoing a surgical operation

Author/year and country of publication	Study aims	Procedure	Study design/number of patients	Methods of information provided to patients	Timing/methods of evaluation	Results
Rossi et al (2004, UK)	Evaluate the effectiveness of using a videotape to give patients information a common orthopedic procedure	Ankle fracture fixation	Randomization/48	Verbal/video	Immediately after receiving information and an average of 10 weeks later/multiple choice questionnaire	Patients who received information on a videotape demonstrated a significant increase in comprehension compared to patients who received this information verbally
Bhangu et al (2008, US)	Compare patient recall of the consent process and desire for information between orthopedic trauma and elective patients	Femoral neck fracture fixation, other trauma operations/elective orthopedic operations	Non-randomization/81	Verbal/verbal and leaflet	First post-operative day/questionnaire	Overall recall of complications was poor in trauma patients; trauma patients desire more information than elective patients
Sahin et al (2010, Turkey)	Evaluate the effectiveness of the consent process and the retention of information in orthopedic patients undergoing trauma and elective surgery	Fracture fixation/elective orthopedic operations	Non-randomization/142	Verbal/written	Post-operative 1-3 days/interview and questionnaire	Trauma patients have higher rate of not recalling any potential complications, and most have not read the consent form
Smith et al (2012, UK)	Assess whether written information improves trauma patient's recall of the risks of surgery	Upper and lower limb fracture fixation	Randomization/121	Verbal/verbal and written	1-17 days (mean 3.2 days)/questionnaire	Risk recall and satisfaction improved when patients receiving written and verbal information compared to verbal information alone

Table 4.2 Methodological quality assessment

	Bhangu et al (2008, US)	Sahin et al (2010, Turkey)	Rossi et al (2004, UK)	Smith et al (2012, UK)
Non-randomized studies				
Case definition	✓	✓		
Representativeness of the cases	X	X		
Ascertainment of exposure	✓	✓		
Same method of ascertainment	✓	✓		
Non-response rate	✓	✓		
Randomized controlled trials				
Sequence generation			X	✓
Allocation sequence concealment			X	X
Blinding of outcome assessment			✓	X
Incomplete outcome data			✓	✓
Selective outcome reporting			✓	✓
Other potential threats to validity			✓	✓

Appendices

Appendix 4-A Data extraction form

Author(s)			
Published year			
Country of publication			
Funding			
Study aim			
Study design	☐RCT		
	☐Cross-sectional study		
	☐Others		
Inclusion criteria			
Exclusion criteria			
Number of participants	Participants screened:		
	Participants enrolled:		
	Participants in the intervention group:		
	Participants in the control group:		
	Participants loss of follow-up		
Participant characteristics	Age:	mean	median

	Gender:	male (n/%)		female(n/%)	
	Ethnicity:				
	Socio-economic status:				
	Acute condition				
	Procedures or operations				
Study setting/department					
Methods of information provided	Intervention	☐verbal	☐written	☐video/multimedia	☐others
	Control	☐verbal	☐written	☐video/multimedia	☐others
Timing of evaluation					
Methods of evaluation	☐Questionnaire				
	☐Interview				
	☐Others				
Outcome measurement	☐Knowledge/comprehension				
	☐Satisfaction				
	☐Others				
Results	RCT				
	Intervention				
	Control				
	Details				
	Cross sectional				
	Details				

	Others
	Details

Appendix 4-B Methodological quality checklist

Non-randomized studies			
Was the case definition adequate?	☐Yes	☐No	☐Unclear
Was the representativeness of the cases adequate?	☐Yes	☐No	☐Unclear
Was the ascertainment of exposure adequate?	☐Yes	☐No	☐Unclear
Was the same method of ascertainment used?	☐Yes	☐No	☐Unclear
Was the non-response rate reported?	☐Yes	☐No	☐Unclear
Randomized controlled trials			
Was the allocation sequence adequately generated?	☐Yes	☐No	☐Unclear
Was the allocation adequately concealed?	☐Yes	☐No	☐Unclear
Was there any blinding of outcome assessment?	☐Yes	☐No	☐Unclear
Was incomplete outcome data adequately described?	☐Yes	☐No	☐Unclear
Had the study selective outcome reporting?	☐Yes	☐No	☐Unclear
Were there other threats to validity	☐Yes	☐No	☐Unclear

CHAPTER FIVE

Manuscript Two

Development and pilot testing of an educational video for informed consent in trauma patients undergoing the surgery debridement

Abstract

Objective

The study objectives are firstly, to develop and pilot test an audiovisual video containing information for the informed consent process for surgery in trauma patients, and secondly, to develop and pilot test the knowledge measure instrument for the understanding of trauma patients for informed consent to surgery and their satisfaction with the informed consent process.

Methods

The modified Delphi technique was applied to reach a consensus among a panel of experts chosen to help develop the video content and questions measuring the understanding of informed consent to specific surgery in trauma patients. Participants were enrolled as a convenience sample of adult trauma patients scheduled to receive the surgery of debridement in the pilot study. The participants completed a knowledge measure and questions evaluating the satisfaction before and after the video education.

Results

The modified Delphi technique comprised three rounds extending over a four-month period. Experts gave the higher scores for the items among the categories of benefits, alternatives, and most items among the category of risks and postoperative complications, as well as some items describing the postoperative care. Experts reached the same consensus on each item after the three-round process. Thirty eligible trauma patients presenting to the emergency department were approached and completed questionnaires in the pilot study. Significantly higher mean knowledge score and satisfactions were noted after participants watched the video compared to before the video education.

Conclusions

The modified Delphi technique is a good method to collect experts' opinions and reach consensus for the contents of informed consent and educational video. The educational video is a useful tool to improve the knowledge and satisfaction of trauma patients in the emergency department. Institutions should give top priority to patient-centered health care, and develop a structured informed consent process to improve quality of care.

Background

The doctrine of informed consent has been recognized as the principal ethical foundation for last five decades. It is also a legal prerequisite in contemporary medicine. It has encouraged patients actively engaged in their health decision-making process concerning the treatments. [1-4]

However, informed consent is more than a process, but is not only a document.[5-8] It is a communication process in which physicians build rapport and relationship with their patients. By this way, it might also help patient-centered decision-making.[9] As most situations occur in emergency settings under time constraint, emotional stress, and physical pain of sudden injury in patients, patients and their families often have difficulty in catching important information essential to providing their consent. [1, 2, 10] Some authors reported that recall is variable and sometimes poor when patients attempt to remember the consent process during acute illness; even, some patients are not able to recall the process at all.[11]

Poor recall is especially marked in trauma patients.[12-15] Due to the unique traits of emergency situations, informed consent in trauma patients is one of the most profound and emotional challenges for patients and their families. During the traditional consenting process, it has been found that trauma patients have difficulty in retaining the vast amount of information presented to them. Patients are often unable to imagine how the surgery would proceed. Consequently, being unaware of what risks and complications they may confront, patients and their families might not give appropriate consent. Therefore, a cooperative effort by the healthcare providers should present critical information in an effective way, and help patients and family members gain adequate knowledge to make their treatment decision even under stressful situations.

In our clinical experience, especially in the emergency department, informed consent is usually obtained by residents or chief residents for most procedures or surgeries. The residents may not have much clinical experience in expecting many unforeseen treatment complications and risks. Furthermore, some residents may not

have good communication skills to explain the information in detail. The quality of information delivered to patients may not be complete. Moreover, the information on the informed consent documents in our hospital is usually simplistic and not validated, or even deficient. Hence, patients' needs may not be properly met by current principles for consent to treatment, particularly in emergency circumstances.

Audiovisual video presents promising results for educating patients in the emergency settings.[16, 17] To our knowledge, using the Delphi technique to develop the education video to improve the informed consent process in trauma patients in emergency department has never been studied.

This study aimed to develop and pilot test educational video containing information for the informed consent process in trauma patients undergoing the surgery of debridement, and develop and pilot test the knowledge measure instrument for the understanding of trauma patients for informed consent to debridement and their satisfaction with the informed consent process.

Methods

Development of the educational video

The first part of the study was to develop the educational video. The first step was to consider which surgery or procedure a video would be developed for trauma patients in the emergency setting. Ideally, a video generally applied to all trauma patients would be what we want. However, each surgery has its unique procedure, risks, benefits, and alternatives, and it was difficult to develop a "one-size-fits-all" video that could be applied to all trauma patients. Hence, we had to develop a video specific to one surgery or procedure. The next question was what specific surgery we might develop. The criteria prioritizing the surgery in the video development included: 1) to benefit the most trauma patients as possible, namely, the surgery that the majority of trauma patients might receive; and 2) not to be life or limb-threatening, because the patients might be sent to the operation room within minutes. Therefore, the final decision was made upon the surgery of debridement for complicated limb wounds.

The next step we had to consider was what content of the video might be included in the development of the video. The content was developed according to the procedure as follows. A panel of experts was invited to participate. Based on the literature, we identified the procedure, risks, benefits, and alternatives for the surgery of debridement. The modified Delphi technique was applied to collect the experts' opinions that contributed to development of the video. The results from the experts were finalized and the script revised for the video. The survey of Degerliyurt et al in an emergency clinic for oral surgery concluded that a thorough informed consent process may disclose too much information to patients and be overwhelming [18]; therefore, the content of the video should contain precise information that patients wanted to know and be within ethical principles and regulations of the law. The expected length of the video was limited to fifteen minutes.

The next step was to contract with a multimedia company to develop the video, after the script had been confirmed. There were several different ways to display the

video, including actor role-play, 2D (2-dimensional) or 3D (3-dimensional) graphics, or interactive computer program. It is believed that using 2D or 3D graphics give promising results, as although an interactive computer program is tailor-made for patients and the results are most promising [19], the disadvantages are higher cost and longer production time. The actors' play may look real, but may result in patient discomfort when watching the video, and details of the surgical procedure may be difficult to display; therefore 2D or 3D graphics was chosen for the development of the video. The cost of 3D graphics is higher than 2D graphics. The developed video contained visual and audio narratives. The audio narrative assisted in describing what was displayed in the video. Subtitles and captions were added for patients to read. After deciding on all the details, a contract with the multimedia company determined that the video would be finished on time and be suited to our needs. The initial version was sent to experts for reviewing, and their comments and opinions were taken into consideration with the video being revised to the final version.

The Delphi technique

The modified Delphi technique was applied to reach a consensus among a panel of experts who were chosen to help develop the video content and questions measuring the understanding of informed consent to specific surgery in trauma patients. In this study, several experts from different fields with a variety of expertise, including trauma surgeons, nurses, informed consent experts, lawyer, patients who had previously received the surgery of debridement, were invited to participate in this Delphi round after experts' agreements. Each expert was chosen by recommended by two specialists from Kaohsiung Medical University Health Care System. The Kaohsiung Medical University Health Care System include one tertiary medical center with more than one thousand and six hundred beds, and two metropolitan hospitals with more than eight hundred beds in total. The patients were recommended by nurse practitioners worked in the plastic surgical ward.

The modified Delphi technique may not use the open questions to collect the experts' opinions in the first Delphi round, because the open questions may pose

difficulty in responding and the experts' response rate may be decreased. Furthermore, by combining the third and fourth Delphi round, the modified Delphi technique has only three rounds. Brooks reported that the three-round investigation might be enough for experts to make a consensus.[20]

During the first step, a script containing the informed consent information in terms of the procedure, risks, complications, benefits, and alternatives for the surgery was developed and summarized based upon the reports from the literature.[21-28] In addition to the informed consent information, the following topics were considered in the video content, including how to choose the appropriate procedure, the preparation of the surgery, anesthesia, and post-operative recovery and care. The experts were asked to provide their opinions on these items of the script draft, in which they might consider what was important for trauma patients during the informed consent process. The questionnaire was sent to the experts by e-mail and returned when completed. The end of the questionnaire provided a space for experts to write down other comments.

After receiving the first round questionnaire, the investigators revised the items of the script draft as experts advised. All items together with the additional comments from the experts formed the second round questionnaire. During the second round, the questionnaire was sent to the experts by email, and the experts were asked to rank the importance and appropriateness for each item on the Likert five-point scale. After receiving and analyzing the result of the second round questionnaire, the investigators summarized which consensus was reached. An abstract with the consensus and the result showing the minimum value, maximum value, mean and median for each item from each participant, providing the chance to compare with others' opinions and to change their decision if they wanted together with a third round questionnaire, was sent to the experts by e-mail. The experts were asked to complete the third round questionnaire. The same ranking procedure was performed for the third round. The consensus was defined as the mean score of the item for the importance and appropriateness was equal or above 3.75. The difference of experts' rating between

the second and third round for each item was also compared.

The knowledge measure instrument

The other part of the study was to develop the knowledge measure instrument. Based on the literature, there is no developed measurement instrument which can be applied to measure the understanding of trauma patients regarding informed consent for surgery. The knowledge measure instrument should be developed specifically for the study to measure the understanding of trauma patients about the informed consent.

The questionnaire collected the data of patient demographics, including age, gender, and level of education. The questions measuring the patient knowledge about the informed consent included the content of video in which the consensus of the experts reached. Each question was equally weighted. The questions were in written form with multiple-choice format. About 20 questions were developed, and they were distributed to the panel of experts. The experts were asked to rate on a five-point scale, each picked question from “strong agreement” to “strong disagreement”. The results of the rating were analyzed. The top 13 questions the experts ranked were picked for the pilot test.

The measure instrument was piloted on 10 subjects. The subjects were selected from the emergency department. Questions that were correctly answered by more than 85% of subjects and those that poorly correlated with the total scores were replaced. The results of the study were used to identify problematic questions, and then the measurement instrument was revised. The instrument was administered in the pilot test of the study. The questions were further eliminated if the correction rate had no statistical significance in the pilot test.

Pilot study

Participants were enrolled on a convenience sample of adult trauma patients scheduled to receive the surgery of debridement. The participants had received the oral information from healthcare providers and completed a knowledge measure as baseline before the video education. Participants watched the educational video illustrating the surgical procedure and its benefits, risks, and alternatives at their

bedside on a portable computer. After watching the video, all participants were asked to complete a knowledge measure again. Questions using the 5-point Likert scale were asked to evaluate the satisfaction with the educational video before and after the educational session.

Data process and statistical analysis

Data collected from patients was recorded by participant number, without any specific identification to the patient. This method may protect patient privacy and secure patient confidentiality. Descriptive statistics was used to analyze the baseline characteristics of the participants. Mean and standard deviations were calculated for continuous variables if they were normally distributed, and proportions were calculated for categorical variables. The difference of experts' rating for each item between the second and third round was compared using Wilcoxon signed-rank test. The exact McNemar's test was used to compare the correction rate of knowledge test for each question before and after video education. Mean scores of before and after educational video on knowledge measure and patient satisfaction were calculated and analyzed. Changes in participation between before and after educational video knowledge were compared using paired *t*-test, and changes in satisfaction ratings were compared using Wilcoxon signed-rank test.

All data analysis was performed with the Stata version 10.0 (StataCorp, College Station, TX).

Results

Demographics of experts

Sixteen experts from different fields with a variety of expertise, including trauma surgeons, nurses or nurse practitioners, member of the ethics committee, and a lawyer and patients who had received the surgery of debridement before were invited to participate in the Delphi round after experts' agreements. The baseline characteristics of experts are provided in Table 5.1. The most common age group for the experts was 30-39 years, and for the majority, academic education was at college level.

Delphi three-round process

The Delphi technique comprised three rounds extending over a four-month period. After the first round, the questionnaire items were revised and rephrased according to experts' suggestions. The results of the second and third round for informed consent in terms of benefit, procedure, risks and post-operative complications, and alternative are provided in Table 5.2. Experts gave the higher scores for the items among the categories of benefits, alternatives, and most items among the category of risks and postoperative complications. Experts gave the lower scores for some items (item 1.3, 1.4, 1.6, 1.7), mainly describing the detailed surgical procedure and anesthesia, among the category of procedure on the second round, but reached consensus on the third round. The results of the second and third round for post-operative wound care are provided in Table 5.3. Experts gave the higher scores for the items describing the purpose, appropriate timing and frequency of ice packing and hot packing, and the procedure of changing dressings. The items with significant difference between second and third round were also identified. Many items (4.7.2, 4.7.3, 4.7.4, 4.7.6, 4.7.7), mainly describing the symptoms of possible wound infection, had significant difference at the second and third round. Experts reached the same consensus on each item after the three-round process.

The pilot study

During the study period, 30 eligible trauma patients presenting to the

emergency department were approached and completed questionnaires. The baseline characteristics of participants who completed the questionnaires are provided in Table 5.4.

The distribution of correction rate before and after the video education for each question on knowledge measure is provided in Table 5.5. The top 13 questions the experts ranked had been picked, and one question was replaced because it was correctly answered by more than 85% of subjects when the knowledge measure was piloted on 10 subjects. Two questions were further eliminated because the correction rate before and after the video education had no statistical significance in the pilot test. The final knowledge measure comprised ten questions, and these were equally weighted and scored.

The results of knowledge scores before and after the video education are distributed and presented in Table 5.6. A significantly higher mean knowledge score is noted after participants watched the video compared to before the video education. The average knowledge score before participants watched the video was 55.33, and 78.33 after watching the video.

The results of ratings of satisfaction are distributed and presented in Table 5.7. A relatively high percentage of patients expressed satisfaction with the informed consent process with the video for the surgery of debridement. A relatively high percentage of patients indicated that they comprehended the information the video provided for the surgery of debridement and that it helped them make a decision for the surgery.

Discussion

We report the result of developing an educational video to improve trauma patients' comprehension and satisfaction for the informed consent process in the emergency department. The educational video contains satisfactory information developed by a panel of experts for trauma patients by the modified Delphi method. The video also demonstrated the information of the informed consent for the surgery of debridement and pilot study revealed that the video showed a promising result for better information delivery and improved satisfaction for trauma patients. Furthermore, evaluating patients' understanding is one very important operational measurement for the success of informed consent process. No reliable and valid measure has been developed to access patient understanding of the surgery, in terms of the benefits, risks, alternatives, and postoperative care in the literature. In our study, the knowledge test developed by a panel of experts had face validity and included information that the authors believed patients had to know before consent was signed for the surgery of debridement. The knowledge measure and satisfaction tools had been scientifically developed and piloted, and its success had been validated. To our knowledge, this is the first study report using the Delphi technique to collect experts' opinions and reach consensus for the contents of informed consent and develop an educational video for the informed consent process, and also the first study to develop such a video for informed consent in trauma patients.

How much information we should provide for patients during informed consent process remains controversial.[8, 29, 30] Though the law mandates healthcare providers disclose information concerning the procedure, risks, benefits, and alternatives for patients, to what extent, still remains a challengeable issue. Reasonable personal and professional standards provide healthcare providers with reference guides to deliberate and deliver adequate information to patients[1, 7, 29-32]; however, progress in trauma treatment is moving rapidly [33, 34], and in our opinion, whether the professional standards could appropriately guide healthcare providers or not is open to further exploration.

Furthermore, the unique characteristics of trauma patients who might have severe physical pain as well as emotional stress interfere with them absorbing important information delivered to them to make the medical decision on one hand, and on the other, when healthcare providers confront each patient with a complicated condition, the decision how to convey complicated information, how much to convey, and by what means, if various means are available, remains a real challenge.

Although in many hospitals, there are written informed consent forms with the explanation of the procedure, risks, alternatives in detail, it should not be presumed that each patient can always understand all the information given to them concerning their case. Moreover, it might be said that such written consent is generally designed for the protection of clinicians and hospitals from litigation rather than for the benefit for the patients.[8, 31] This is not concordant with the core values and principles of informed consent, and is possibly harmful to the patient-physician relationship. Therefore, physicians and institutions should develop strategies to improve the informed consent process in the best interests of patients.

The investigator believes that there is a deficiency for international consensus about how to develop an adequate informed consent form and by whom as well as what the informed consent documents should specifically include. Though there are principles and guidelines to recommend the content of the informed consent, many factors should be considered. For example, one of the most difficult questions that surgeons have to answer is: what are the risks for the surgery?[30] Though there is a new tool for healthcare providers and patients to estimate the risks of postoperative complications (http://riskcalculator.facs.org), trauma is not included. The investigator has inspected many informed consent documents and found variety of the content in informed consent forms. Some of the documents were very long, and some were short. The main categories (procedure, benefits, risks/complications, and alternative) were included, but the content within the categories varied. In particular, the risks were described differently. Some were quite detailed, laying out all possible risks and complications explaining the possibility, even when the complication is very rare and

chance is very small. Some were described in general without the explanation of any possibility. Therefore, there might be a need for a universal consensus and standardized format for informed consent document for trauma patients and further research is needed for this field.

In our study, the investigators proposed the methodology that can be applied to develop the content of informed consent for specific surgery. The content of informed consent might be different respecting for individual hospital or even different culture in different countries. We recommended that the development of the content of informed consent should base upon a scientific method by integrating the opinions of different stakeholders. The institutions are able to develop the content of informed consent in reference to their own policies under the principles of ethics and regulations of laws. The countries are also able to develop the unique content of informed consent based upon their different cultures.

Informed consent is a vital process to communicate with patients and families and build trust. It is the process for healthcare providers to invite patients and families to share each other's values, beliefs, and opinions in making the best medical decision to maximize benefit to the patient. Therefore, we believe it is important to include the patients in discovering what they are concerned with most, and then reach a consensus in the development of the informed consent contents. Kusec et al recommended that it is essential to involve patients to take part in the development of informed consent information and to dedicate the method for developing educational materials for improving understanding. [35] In our study, several patients were included in our panel of experts to provide precious viewpoints.

The Delphi technique may secure a "group" consensus by using a structured process in which many rounds of interviews are conducted by questionnaires.[36-39] The process is conducted anonymously to grant every participant an equal chance to express his ideas and thoughts in an impartial manner. Opinions and reactions collected from participants would be analyzed with the same weight and importance. Choosing adequate experts in participating in the study is important for Delphi

technique success. If the chosen experts represent the areas under the study interest, content validity may be ensured.[40] In our study, we included several experts from different fields with a variety of expertise, including trauma surgeons, nurses, informed consent experts, a lawyer, and patients who had previously received the surgery of debridement were invited to participate in this Delphi round. In our opinion, the content validity was ensured.

The Delphi technique has several advantages. One of them is that opinions from every expert may be dealt with equally.[37, 38] Experts may compare their own opinion with others' and re-ponder the matter to shape their values and opinions. The opinions from experts could be revised accordingly. In our study, experts had different ratings for some items in the second round; however, consensus was reached after comparing their own opinion with others in the third round. In our opinion, the Delphi technique is a useful tool to build consensus regarding the content of informed consent and helps further develop an educational tool.

Trauma patients have unique characteristics and obtaining valid informed consent from them is difficult and exactingly challenging. When an accident occurs, most of the time, trauma patients have to make medical decisions in a very short time frame. Very often, they may not absorb that much information exposed to them. Furthermore, if the surgery is very complicated and has many possible risks and complications, it may be arduous for the healthcare providers to enable the patients to comprehend the information, help them make a medical decision, and then obtain the patient's consent.

Most patients might be inclined to have more information when making medical decisions.[41] One study supported that information received by surgical patients is an important determinant of patient satisfaction, and suggested that more attention should be devoted to this area.[42] Many strategies have been adopted to support better understanding before procedures or surgeries, including using illustrative materials, leaflet and pamphlets, video description, and interactive computer programs [14, 16, 17, 19, 43-54] as well as "repeat back" strategy have

been adopted to bring about better patient understanding [55, 56] These strategies have revealed some advantages and limitations. Bhangu et al reported that orthopedic trauma patients had poor recall of the operation and complications, and repeated verbal explanation and leaflets should be provided routinely.[12] Several studies have reported that giving written materials to the patients before receiving procedures might increase the patient's knowledge and is a useful tool for patients.[41, 57] Although written material usually requires patient's active collaboration and compliance, and transfer of knowledge concerning procedures and risks to the patient is often limited. Studies have reported that significant percentages of patients do not even read consent forms before signing.[13, 58] Another study concluded that trauma patients often need repeated verbal explanations of the procedure and its potential complications rather than just providing them with written information. [20]

Several studies have also shown that using video-assisted methods to educate patients resulted in better patient satisfaction and improved patient knowledge of the procedures and risks.[41, 50-52, 57, 59-62] Although most of these studies focused on elective procedures or surgeries, problems of patient understanding and information retention should be greater in emergency settings, so is recommended that institutions develop effective educational tools to foster the informed consent process. Using information aids may elicit better communication between physicians and patients and incidentally better deliver standard information. In our study, the patients had significantly higher knowledge score and satisfaction after video education, and we believe that the educational video is a very good tool for the informed consent process in trauma patients.

Recent technological advances in portable and tablet computer technology have provided good opportunities for improving patient education for surgery [10], as portable computers have larger screen displays, larger memory storage, and good image resolution, so can more easily deliver educational information and videos with good quality presentation.; consequently, the use of innovative portable

computer technology may help preoperative education in trauma patients requiring emergency surgery.

In sum, the investigators also recommended that the institutions and healthcare providers should provide standardized and structured information for patients to promote their undertakings and satisfaction. An informational aid like the video could provide such information and could be considered to improve the consent process for trauma patients in the emergency department. However, it still must be emphasized that such tools cannot and should not replace the entire process of informed consent, as a vital process where patients and healthcare providers have a good opportunity to express their own opinions and values, exchange information, and make themselves mutually understood. This is principal in building trust and a good relationship between patients and healthcare providers through appropriate communication in the informed consent process.

Our study had several limitations. First, though the experts in this study comprised a variety of specialties, it was possible that their opinions might not have reflected the whole picture for the matter studied. Further studies might be needed to include more experts with a broader spectrum of specialties to provide more thorough opinions. Second, the injury severities of trauma patients vary and might have an influence on their consent process and perceptions of satisfaction. Future studies are needed to explore these associations. Third, the pilot test was not a randomized controlled study design, there might be many confounders limiting our inferences, as noted by Eccles et al. in their discussion of research designs for evaluating the effectiveness of change and improvement strategies.[63] Further randomized controlled studies will be needed to confirm the effectiveness of the educational video compared to the routine informed consent discussion on trauma patients in the emergency department. Finally, the pilot study was conducted in one institution and the results might not be generalizable to other institutions.

Conclusions

Informed consent is an important issue for trauma patients in the emergency department. Healthcare providers and institutions should develop strategies to improve the informed consent process to stand for the best interest of patients. The Delphi technique is a good method to collect experts' opinions and reach consensus for the contents of informed consent and educational video. The educational video is a useful tool to improve the knowledge and satisfaction of trauma patients in the emergency department. Institutions should give top priority to patient-centered health care, and develop a structured informed consent process to improve quality of care.

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Table 5.1 Baseline characteristics of the Delphi experts.

Characteristic	No.	%
Specialty		
Physician	5	31.2
Nurse or Nurse practitioner	5	31.2
Patient	4	25.0
Member of Ethics committee	1	6.3
Lawyer	1	6.3
Age		
20-29	1	6.3
30-39	9	56.2
40-49	4	25.0
50-59	2	12.5
Gender		
Female	7	43.8
Male	9	56.2
Education		
College	10	62.5
Post-graduate	6	37.5

Table 5.2 Delphi results for benefit, procedure, risks and complications, and alternatives

Category	Item No.	Item	Importance				Appropriateness			
			Mean	Median	Min	Max	Mean	Median	Min	Max
Benefit	1.1	Surgical debridement is the procedure to remove necrotic tissue and foreign bodies from wounds, and the fastest and most effective way to clean the wounds. It may prevent infection and improve the process of wound healing.	4.56/4.63	5/5	3/3	5/5	4.38/4.31	4.5/4	3/3	5/5
Procedure	1.2	The procedure may be performed at bedside, or in the operation room, if the wound is too deep, large, or involves the important tissue, such as nerve, vessel or muscle, in order to decrease the possibility of wound infection and other complications.	4.5/4.69	5/5	2/4	5/5	4.75/4.63	5/5	4/3	5/5
	1.3	When the local anesthesia is chosen, the surgeon will inject the medication to anesthetize the region where the procedure will be performed.	3.94/4.44	4/4.5	1/3	5/5	4.00/4.19	4/4	2/3	5/5
	1.4	The epidural anesthesia may be chosen to anesthetize the lower part of the body by injecting the medication into the lumbar spinal cord when the procedure will be performed over the lower part of the body.	3.63/3.94	4/4*	2/2	5/5	3.94/4.00	4/4	3/3	5/5
	1.5	General anesthesia is to block the feeling of pain over the whole body, and you may fall asleep in the surgical procedure.	4.00/4.31	4/4	3/4	5/5	4.19/4.13	4/4	3/3	5/5
	1.6	The surgeon will clean the wound and remove the contaminants as much as possible with normal saline.	3.81/4.31	4/4	1/3	5/5	4.25/4.06	5/4	1/3	5/5
	1.7	The surgeon may use surgical instruments to remove the necrotic tissue repeatedly until the wound is clean.	3.69/4.00	4/4	1/3	5/5	3.94/3.94	4/4	1/3	5/5

Table 5.2 Delphi results for benefit, procedure, risks and complications, and alternatives (continued)

	1.8	When the procedure is finished, the surgeon will close the wound layer by layer. If the wound is not closed instantly, the wound will be cared for openly.	4.56/4.88	5/5*	4/4	5/5	4.56/4.50	5/5	3/3	5/5
	1.9	The timing of wound closure will depend on the injured mechanism, the location of the wound, and the possibility of wound infection.	4.44/4.63	5/5	3/4	5/5	4.56/4.69	5/5	3/4	5/5
	1.10	The skin will be closed by suture, adhesive tape, or staples, and covered by sterile gauge or dressing.	4.13/4.25	4/4	3/3	5/5	4.13/4.50	4/5	3/3	5/5
Risks and postoperative complications	2.1	When the debridement is performed, deep tissue such as vessels, tendons, or nerves might be injured, and the complications will include bleeding, tendon injury, nerve injury, postoperative range of motion limitation of limbs, wound pain, or permanent scarring, etc.	4.25/4.50	5/5	3/3	5/5	4.38/4.31	4.5/4	2/2	5/5
	2.2	Bacteria over the skin might affect the deep tissue and cause infection, and the rate of infection might differ and depend on the cause of injury, mechanism, and location of the wound.	3.69/4.13	4/4	2/3	5/5	4.00/3.69	4/4	2/2	5/5
	2.3	Past illness might increase the risks of the procedure and postoperative complications, such as Diabetes Mellitus, using steroid and anti-immune drugs, anti-coagulants, and immune-compromised diseases.	4.94/4.81	5/5	4/4	5/5	4.81/4.69	5/5	4/4	5/5
	2.4	Smoking, poor nutrition, or poor circulation might increase the risks of the procedure and postoperative complications.	4.69/4.81	5/5	4/4	5/5	4.81/4.81	5/5	4/4	5/5
	2.5	Unforeseen disorders might occur, such as shock, or arrhythmia.	4.81/4.81	5/5	4/4	5/5	4.63/4.88	5/5*	4/4	5/5

Table 5.2 Delphi results for benefit, procedure, risks and complications, and alternatives (continued)

	2.6	Complicated wounds need to come back to the clinics regularly to decrease the complications.	4.56/5.00	5/5*	3/5	5/5	4.75/4.88	5/5	3/4	5/5
Alternative	3.1	Wound management might be performed in other ways, such as a bio-artificial dressing might be used to debride the wound, but it takes 2~4 weeks, and has the increased risk of wound infection. If you have any questions concerning the treatment, please discuss these with your physician.	4.38/4.38	4.5/4	3/4	5/5	4.19/4.31	4/4	3/3	5/5

*$p<0.05$

Table 5.3 Delphi results for wound care section

Category	Item No.	Item	Importance				Appropriateness			
			Mean	Median	Min	Max	Mean	Median	Min	Max
Wound care	4.1	Ice packing over the wound is recommended during one to three days after injury, and it can be done ten to fifteen minutes for three to four times per day. Ice packing might stop the bleeding and alleviate the swelling as well as pain of the wound. In the meantime, the injured limb should be elevated above the heart to alleviate the swelling and discomfort, and over-activity for the injured limb should be avoided.	4.81/4.94	5/5	4/4	5/5	4.94/4.94	5/5	4/4	5/5
	4.2	Hot packing is recommended after 3 days of injury to improve the circulation alleviating the swelling of wounds.	4.19/4.50	4/5	3/3	5/5	4.13/4.69	4/5*	3/4	5/5
	4.3	Dressing change is suggested on the second day after injury for wounds. Normal saline can be used to clean the wound. The dressing should be kept dry and might be changed after taking a bath daily.	4.44/4.63	5/5	2/3	5/5	4.50/4.81	5/5*	3/4	5/5
	4.4	Please follow the orders of your doctor and other professionals to take care of your wound. For wound care, you may need:	4.81/5.00	5/5	4/5	5/5	4.69/4.69	5/5	4/4	5/5
	4.4.1	Two clean disposable gloves	4.13/4.38	4/4	3/4	5/5	4.19/4.25	4/4	3/3	5/5
	4.4.2	Normal saline	4.69/4.63	5/5	4/4	5/5	4.75/4.69	5/5	4/4	5/5
	4.4.3	Small gauze or sterile cotton swab to clean the wound	4.44/4.69	4.5/5	3/4	5/5	4.50/4.75	4.5/5	4/4	5/5
	4.4.4	Large gauze to cover the wound	4.31/4.69	4/5*	3/4	5/5	4.44/4.69	4/5*	4/4	5/5
	4.4.5	Adhesive tape	4.38/4.50	5/4.5	3/4	5/5	4.50/4.50	5/4.5	3/4	5/5

Table 5.3 Delphi results for wound care section (continued)									
4.5	The procedures of changing the dressing								
4.5.1	Clean and wash your hands first, and put on the clean gloves. Then take off the covered gauze from the wound.	4.31/4.69	4/5	3/4	5/5	4.56/4.38	5/4.5	3/3	5/5
4.5.2	Observe the color and odor of discharge from the wound on the gauze.	4.19/4.63	4/5	2/4	5/5	4.31/4.31	4/4	3/3	5/5
4.5.3	If the gauze adheres to the wound, normal saline might be used to rinse the gauze, and then the gauze might be removed gently a few minutes later.	4.5/4.56	4.5/5	4/4	5/5	4.38/4.75	4/5*	4/4	5/5
4.5.4	You may use normal saline to rinse small gauze or sterile cotton swabs.	4.38/4.50	4/4.5	3/4	5/5	4.56/4.56	5/5	4/4	5/5
4.5.5	The wound can be cleaned by small gauze or sterile cotton swab from up to down or from in to out circularly, and the gauze and sterile cotton swab should be dropped into a zip bag after cleaning the wound.	4.69/4.50	5/4.5	4/4	5/5	4.31/4.38	4/4	4/4	5/5
4.5.6	Each wound needs a new gauze or sterile cotton swab.	4.56/4.63	5/5	3/4	5/5	4.75/4.44	5/4.5*	4/3	5/5
4.5.7	In principle, the skin area within 10 cm of the wound should be cleaned by the gauze and sterile cotton swab from up to down, and drop the used gauze and cotton swab into a zip bag.	4.00/4.00	4/4	2/3	5/5	4.56/4.00	5/4*	4/3	5/5
4.5.8	After cleaning the wound, the sterile cotton swab can be used to remove any discharge from the wound surface.	4.00/4.19	4/4	3/3	5/5	4.25/4.31	4/4	3/3	5/5
4.5.9	Ointment may be applied to the wound, if indicated.	4.50/4.50	4.5/4.5	4/4	5/5	4.56/4.50	5/4.5	4/4	5/5

Table 5.3 Delphi results for wound care section (continued)									
4.5.10	When opening the bag with large gauzes and putting on another pair of clean gloves, you can hold the corner of the gauze and place the center of the gauze over the wound to cover it.	4.25/4.13	4/4	3/3	5/5	4.56/4.31	5/4	4/3	5/5
4.5.11	Stick on the gauze with tape. Take off the gloves and drop them into the trashcan. At last, wash and clean your hands.	3.88/4.00	4/4	3/3	5/5	4.19/4.13	4/4	3/3	5/5
4.6	If you are allergic to tape, you may use low-allergy tape or a bandage to manage the wound.	4.19/4.25	4/4	2/3	5/5	4.19/4.19	4/4	2/3	5/5
4.7	Observe the wound carefully; tell your doctor or other professionals and go to the clinic as soon as possible, if								
4.7.1	Redness is noted over the wound or around the wound.	4.50/4.63	5/5	3/4	5/5	4.56/4.69	5/5	3/4	5/5
4.7.2	The yellowish and green discharge has a bad odor, or more discharge is noted from the wound.	4.44/4.94	5/5*	3/4	5/5	4.63/4.94	5/5	3/4	5/5
4.7.3	Bleeding is noted again, or cannot be stopped even with ten minutes of direct pressure.	4.63/5.00	5/5*	3/5	5/5	5.00/5.00	5/5	5/5	5/5
4.7.4	Swelling or pain is noted around the wound.	4.19/4.50	4/4.5*	3/4	5/5	4.69/4.69	5/5	3/4	5/5
4.7.5	The skin edge of the wound breaks down over 0.5 cm.	4.31/4.31	4/4	3/3	5/5	4.56/4.50	5/4.5	4/4	5/5
4.7.6	The skin edge of the wound remains wet.	4.13/4.44	4/4.5*	3/3	5/5	4.50/4.44	5/4.5	3/3	5/5
4.7.7	Your body temperature is elevated over 38.5℃.	4.56/4.88	5/5*	4/4	5/5	4.75/4.81	5/5	4/4	5/5
4.7.8	You have any questions concerning wound condition and care.	4.19/4.63	4.5/5	2/4	5/5	4.50/4.50	5/4.5	2/4	5/5

*p<0.05

Table 5.4 Baseline characteristics of participants in pilot study.

Characteristic	No.	%
Age		
<20	6	20.0
20-29	9	30.0
30-39	7	23.3
40-49	2	6.7
50-59	3	10.0
>60	3	10.0
Gender		
Female	16	53.3
Male	14	46.7
Education		
≤ High school	14	46.7
College	16	53.3

Table 5.5 Distribution of correction rate for each question.

	Questions	Before Correction rate (%)	After Correction rate (%)	p-value
1.	The purpose of the surgery for debridement is to (1) relieve pain (2) examine the infective pathogen (3) to remove necrotic tissue and foreign body from wounds (4) all of the above.	36.7	60.0	0.016
2.	Which of the following is the risk for surgical debridement? (1) the vessels, tendon, or nerve might be injured (2) Bacteria over the skin might affect the deep tissue and cause infection (3) both of the above	56.7	80.0	0.016
3.	Which of the following might increase the risks of the procedure and postoperative complications? (1) using pain killers (2) using steroids (3) using antibiotics.	43.3	80.0	0.007
4.	Which of the following conditions might increase the risks of the procedure and postoperative complications? (1) imbibing alcohol (2) smoking (3) drinking coffee (4) chewing betel nut.	10.0	43.3	0.002
5.	The appearance of the wound should be observed postoperatively; which of the following is normal? (1) Redness is noted over the wound or around the wound. (2) The yellowish and green discharge has bad odor, or more discharge is noted from the wound. (3) The body temperature is 37℃ (4) The skin edge of the wound remains wet.	26.7	53.3	0.039
6.	When should the ice packing over the wound be started after injury? (1) 1~3days (2) 3~6 days (3) over 6 days.	66.7	100.0	0.002
7.	How long should the ice packing be done every time? (1) 1~5 minutes (2) 10~15 minutes (3) 30~60 minutes.	46.7	83.3	0.007
8.	Which of the following is not the purpose for ice packing? (1) stop the bleeding (2) increase the circulation (3) alleviate the pain	73.3	93.3	0.031
9.	When should the hot packing be applied after injury? (1) 1st day (2) 2nd day (3) 3rd days or later.	70.0	93.3	0.039
10.	If the gauze is adhered to the wound, what do you do when changing the dressing? (1) remove directly (2) use the hyper dioxide to rinse the gauze (3) use normal saline to rinse the gauze	76.7	96.7	0.031

Table 5.6 Participant knowledge score for pilot study. (n=30)

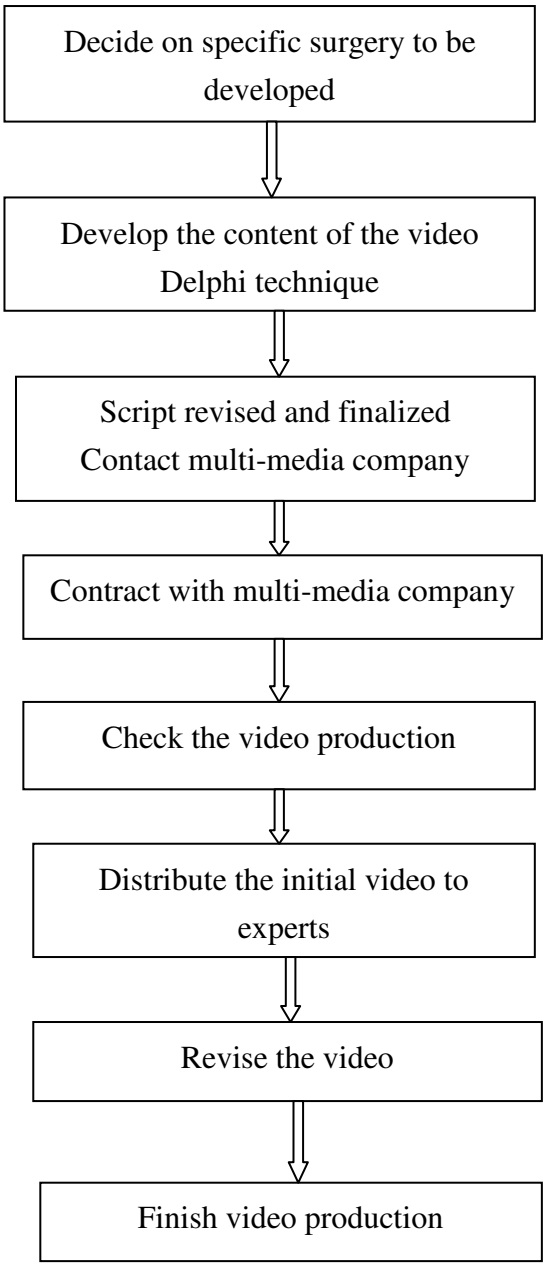
Outcome	before		after		p-value
	Mean	Standard Deviation	Mean	Standard Deviation	
Knowledge score	55.33	18.33	78.33	11.17	0.00

Table 5.7 Distribution of satisfaction ratings of the educational video.

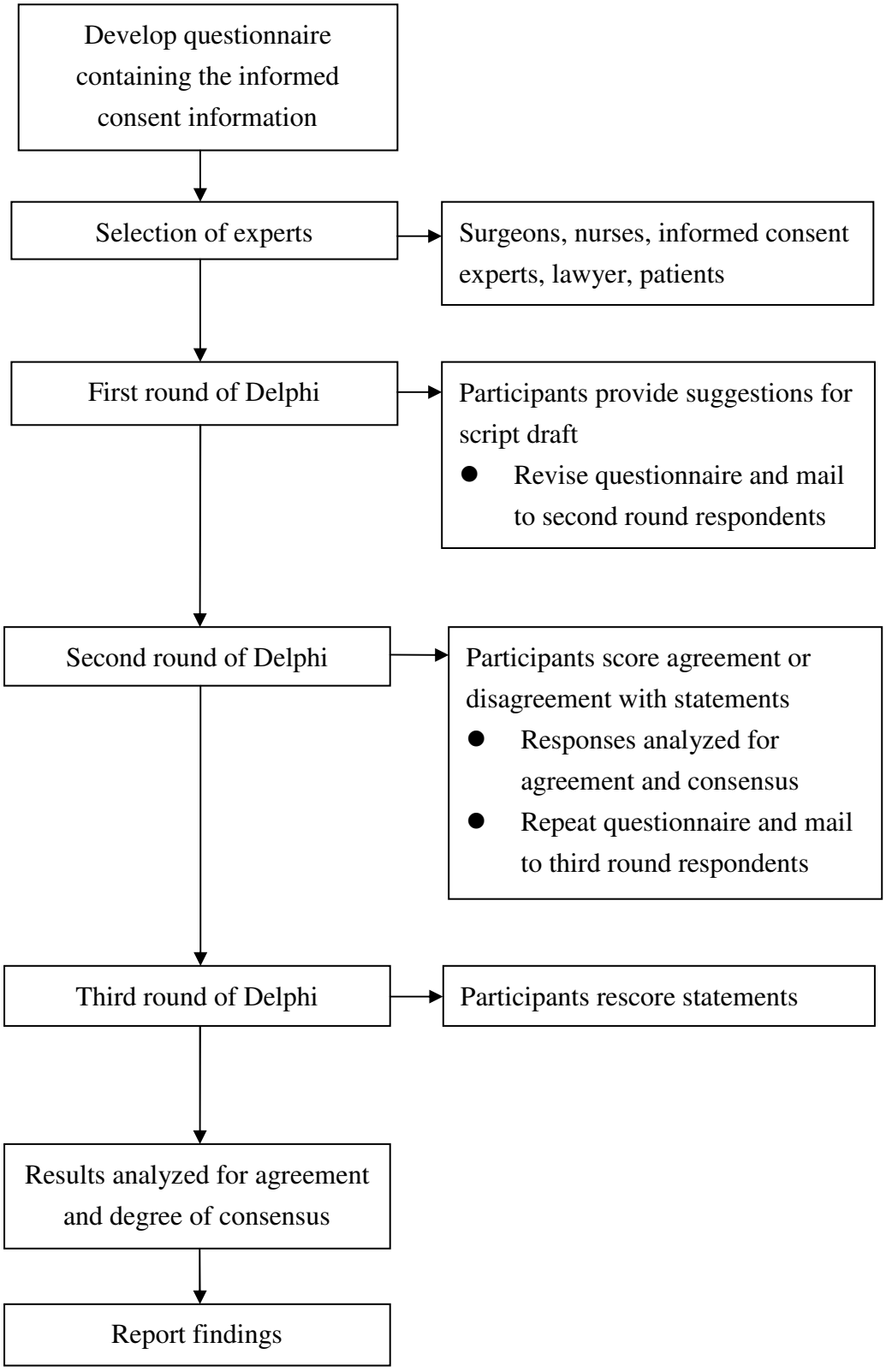
Outcome	Before No (%)	After No (%)	p-value
I can comprehend the information that healthcare providers provided for the surgery			0.00
Strongly agree	7 (23.3)	17 (56.7)	
Agree	19 (63.3)	11 (36.7)	
Fair	3 (10.0)	2 (6.7)	
Disagree	1 (3.3)	0 (0.0)	
Strongly disagree	0 (0.0)	0 (0.0)	
The information that healthcare providers provided can help me make a decision for the surgery			0.00
Strongly agree	9 (30.0)	17 (56.7)	
Agree	19 (63.3)	13 (43.3)	
Fair	2 (6.7)	0 (0.0)	
Disagree	0 (0.0)	0 (0.0)	
Strongly disagree	0 (0.0)	0 (0.0)	
I am satisfied with the informed consent process for the surgery			0.01
Strongly agree	7 (23.3)	18 (60.0)	
Agree	21 (70.0)	12 (40.0)	
Fair	2 (6.7)	0 (0.0)	
Disagree	0 (0.0)	0 (0.0)	
Strongly disagree	0 (0.0)	0 (0.0)	

Appendices

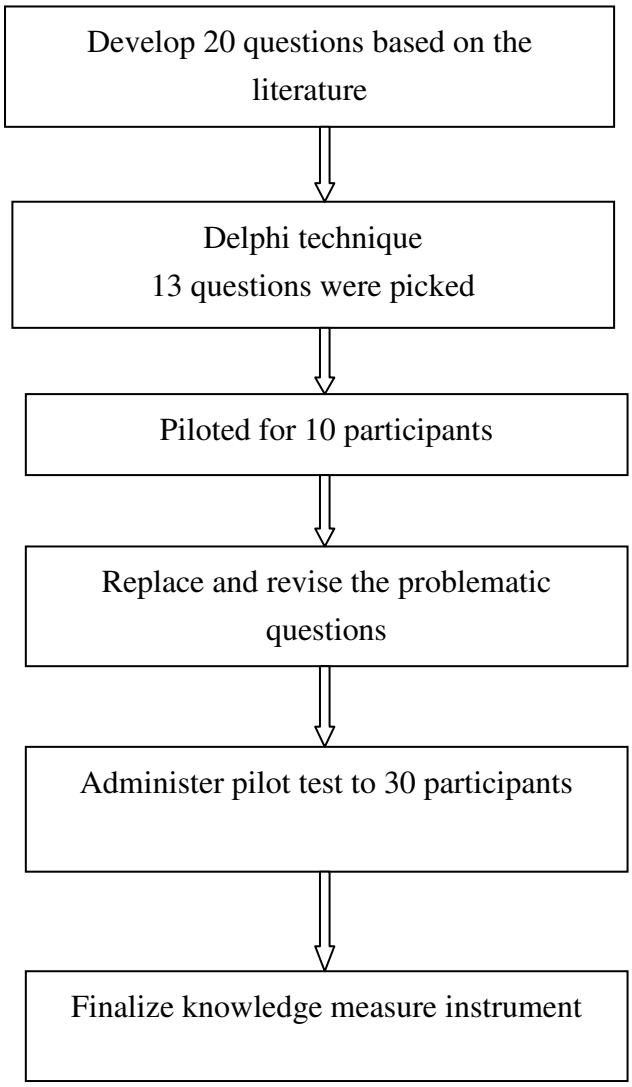
Appendix 5-A Flow diagram for video development



Appendix 5-B Delphi technique

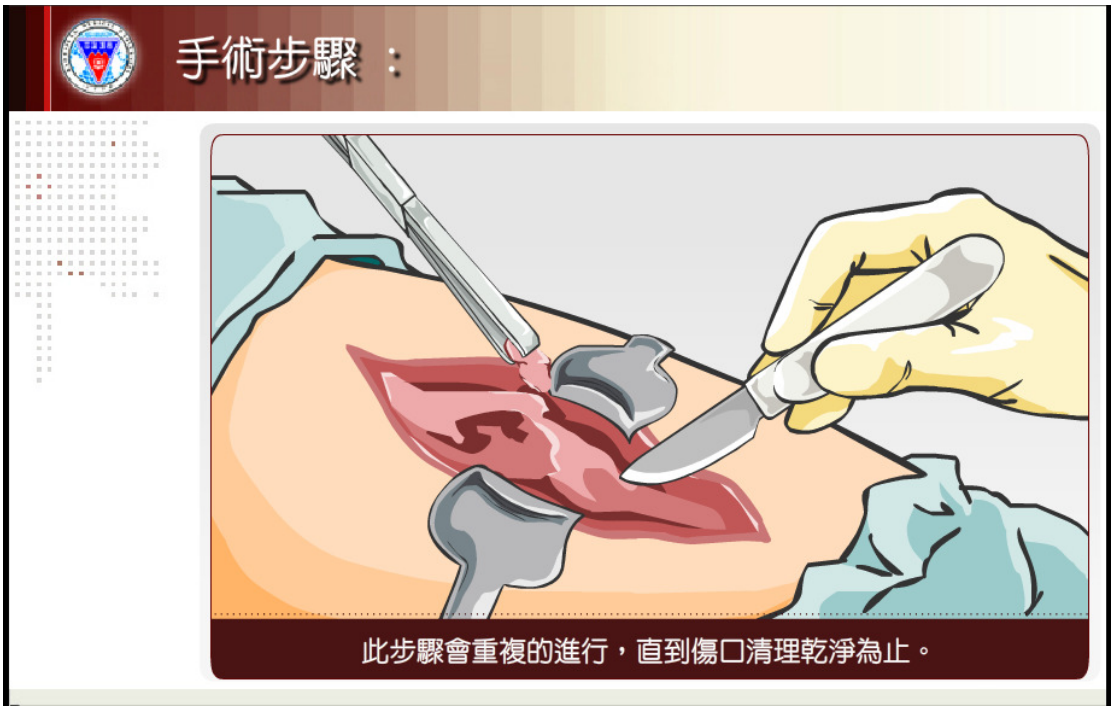


Appendix 5-C Flow diagram for knowledge measure instrument development



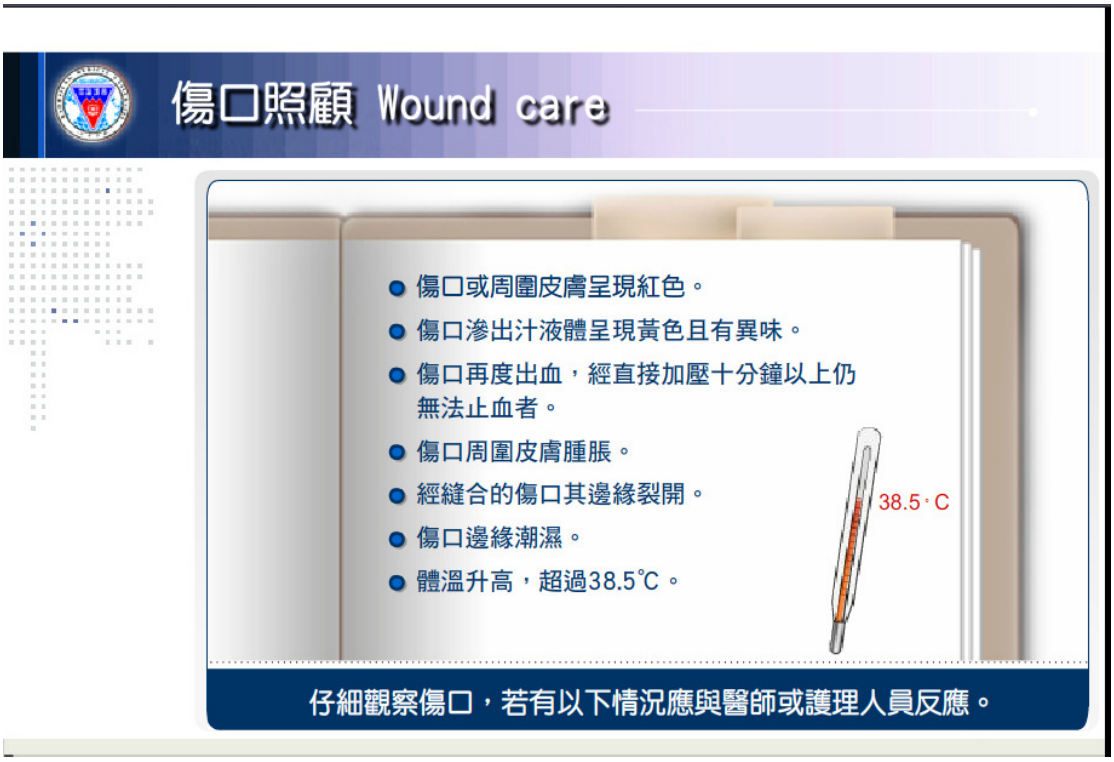
Appendix 5-D (Figure) Benefit of the surgery

Appendix 5-E (Figure) Procedure of the surgery



Appendix 5-F (Figure) Risks and complications of the surgery

Appendix 5-G (Figure) Post-operative care



(The video was produced by the Center for Development of Multimedia Digital Material of Kaohsiung Medical University.)

Appendix 5-H Video script Chinese version

手術步驟

清創手術就是藉由外科方式將傷口或其周圍的壞死組織、外來物質移除的手術，是清理傷口時，最快也最有效率的方法。清創手術能阻止組織繼續壞死，避免傷口持續惡化，幫助肉芽、組織生長，促進傷口癒合。清創手術可以在床邊進行，然而若傷口過深或接近重要臟器、組織時，則會於手術室中執行。
手術前您會被要求穿上手術衣，

可能會需要藉由靜脈注射。

接著會被移至手術台。

醫師會將手術區域及其周圍的毛髮清除並塗上消毒液。

之後會在手術區域覆蓋上無菌單。

然後進行麻醉工作。局部麻醉時，醫師會在不只一個區域注射麻醉藥物，以確保整個手術區域都是麻木的；

另一種麻醉方式為由脊髓注入麻醉藥物讓下半身麻木。

全身麻醉則是阻斷整個身體對疼痛的感覺，您會感覺像睡著一樣。

當麻醉生效後，醫師會在手術區域進行手術。
首先醫師會使用生理食鹽水將傷口之汙染物(如泥土、沙)沖洗乾淨。之後，醫師會用手術鉗將傷口周圍組織拉起，再以剪刀或手術刀取下壞死的組織，此步驟會重複的進行，直到傷口清理乾淨為止。

處置完成後會將肌肉層、其他組織縫合。縫合的時機，會視受傷原因、受傷位置、傷口感染可能性之高低而不同。一般在 6 小時至 5 天不等。在某些病例中，清創手術可能會重複的進行。

表面皮膚會以縫線或 U 形釘閉合。

最後覆上消毒紗布。

清創手術之風險及術後可能的併發症

(1)清創手術進行時，有可能會傷及深層的組織，如血管、肌腱、神經等。造成流血不止、肌腱損傷、神經損傷等併發症。
(2)傷口表面的細菌可能在手術進行時進入深層組織中造成感染。
(3)過去的疾病可能會增加手術的風險及術後可能的併發症。例如糖尿病、使用類固醇及其他免疫抑制藥物、免疫疾病等。
(4)抽菸、營養不佳、循環不佳也可能會增加手術的風險及術後可能的併發症。
(5)其他不可預知之突發性病變。

替代方案

傷口處理可能有其他的方式可以進行，但不一定可行。如果您對於處置方式有所疑慮，請與您的醫師妥善討論其他方式的可行性及相關風險。

傷口照顧

所有創傷傷口皆有感染之可能，請務必保持清潔。受傷之第一天至第三天請為傷口進行冰敷，建議每天執行三至四次，每次十至十五分鐘。冰敷可讓傷口止血，減少腫脹：亦可減緩疼痛感。受傷第三天以後，建議為傷口熱敷，熱敷能促進血液循環，可以消除傷口之腫脹。

所有創傷傷口建議在第二天開始換藥。建議使用乾淨的清潔液或市售之外用生理食鹽水清洗傷口。

照顧傷口時需要：
(1) 2 雙乾淨的拋棄式手套 (2) 生理食鹽水或乾淨清潔液 (3) 清潔傷口用的小塊紗布 (4) 包紮傷口用的大塊紗布 (5) 透氣膠布。

仔細洗淨及擦乾雙手。

帶上手套。

第一步先移除傷口上的包紮紗布。

鬆開膠布邊緣部分，由膠布外側向傷口部分撕膠布。

用另一隻手壓住傷口邊緣的皮膚。

將膠布及包紮的紗布一起拿起，並注意紗布上傷口滲出物的顏色及氣味。

若紗布與傷口沾黏，在紗布上倒一些生理食鹽水或乾淨清潔液。

之後再輕輕將紗布取下。

仔細觀察傷口，若有以下情況應與醫師或護理人員反應。

- 傷口或周圍皮膚呈現紅色。
- 傷口滲出之液體呈現黃色且有異味。
- 傷口再度出血，經直接加壓十分鐘以上仍無法止血者
- 傷口周圍皮膚腫脹
- 經縫合的傷口其邊緣裂開
- 傷口邊緣潮濕
- 體溫升高，超過 38.5℃

將清潔液倒在小紗布上，若不小心倒太多請擠掉過多的清潔液。

將紗布由傷口的上方往下或由內往外清潔，清潔完畢後將紗布丟入封口袋。

每清潔一個傷口就使用一個新的紗布。

原則上，傷口周圍 10 公分的皮膚都要以紗布清潔，清潔時也是由上至下，結束時將紗布丟入封口袋。清潔後，以無菌棉棒拭除傷口表面之分泌物即可。必要時，再將傷口塗抹上藥膏。

清洗並擦乾手。

打開大紗布的包裝。

穿上另一雙乾淨的手套

雙手握在紗布對角的角落上。

將紗布的中心放置在傷口上。

以透氣膠布將紗布牢牢黏貼住。

脫掉手套並丟入封口袋，將封口袋封緊丟入垃圾桶。

清洗並擦乾手。

若皮膚對透氣交部過敏，可以在藥房購買低敏感膠布或使用繃帶包紮傷口。

Appendix 5-I Video script English translation

Benefits

Surgical debridement is the procedure to remove necrotic tissue and foreign bodies from wounds, and the fastest and most effective way to clean the wounds. It may prevent infection and improve the process of wound healing.

Procedure

The procedure may be performed at bedside, or in the operation room, if the wound is too deep, large, or involves the important tissue, such as nerve, vessel or muscle, in order to decrease the possibility of wound infection and other complications.

When the local anesthesia is chosen, the surgeon will inject the medication to anesthetize the region where the procedure will be performed. The epidural anesthesia may be chosen to anesthetize the lower part of the body by injecting the medication into the lumbar spinal cord when the procedure will be performed over the lower part of the body. General anesthesia is to block the feeling of pain over the whole body, and you may fall asleep in the surgical procedure.

The surgeon will clean the wound and remove the contaminants as much as possible with normal saline. The surgeon may use surgical instruments to remove the necrotic tissue repeatedly until the wound is clean. When the procedure is finished, the surgeon will close the wound layer by layer. If the wound is not closed instantly, the wound will be cared for openly. The timing of wound closure will depend on the injured mechanism, the location of the wound, and the possibility of wound infection. The skin will be closed by suture, adhesive tape, or staples, and covered by sterile gauge or dressing.

Risks and postoperative complications

When the debridement is performed, deep tissue such as vessels, tendons, or nerves might be injured, and the complications will include bleeding, tendon injury, nerve injury, postoperative range of motion limitation of limbs, wound pain, or permanent scarring, etc. Bacteria over the skin might affect the deep tissue and cause infection, and the rate of infection might differ and depend on the cause of injury, mechanism, and location of the wound.

Past illness might increase the risks of the procedure and postoperative complications, such as Diabetes Mellitus, using steroid and anti-immune drugs, anti-coagulants, and

immune-compromised diseases. Smoking, poor nutrition, or poor circulation might increase the risks of the procedure and postoperative complications.

Unforeseen disorders might occur, such as shock, or arrhythmia. Complicated wounds need to come back to the clinics regularly to decrease the complications.

Alternative

Wound management might be performed in other ways, such as a bio-artificial dressing might be used to debride the wound, but it takes 2~4 weeks, and has the increased risk of wound infection. If you have any questions concerning the treatment, please discuss these with your physician.

Wound care

Ice packing over the wound is recommended during one to three days after injury, and it can be done ten to fifteen minutes for three to four times per day. Ice packing might stop the bleeding and alleviate the swelling as well as pain of the wound. In the meantime, the injured limb should be elevated above the heart to alleviate the swelling and discomfort, and over-activity for the injured limb should be avoided. Hot packing is recommended after 3 days of injury to improve the circulation alleviating the swelling of wounds.

Dressing change is suggested on the second day after injury for wounds. Normal saline can be used to clean the wound. The dressing should be kept dry and might be changed after taking a bath daily. Please follow the orders of your doctor and other professionals to take care of your wound. For wound care, you may need:

- Two clean disposable gloves
- Normal saline
- Small gauze or sterile cotton swab to clean the wound
- Large gauze to cover the wound
- Adhesive tape

The procedures of changing the dressing:

- Clean and wash your hands first, and put on the clean gloves. Then take off the covered gauze from the wound.
- Observe the color and odor of discharge from the wound on the gauze.
- If the gauze adheres to the wound, normal saline might be used to rinse the gauze,

and then the gauze might be removed gently a few minutes later.

- You may use normal saline to rinse small gauze or sterile cotton swabs.
- The wound can be cleaned by small gauze or sterile cotton swab from up to down or from in to out circularly, and the gauze and sterile cotton swab should be dropped into a zip bag after cleaning the wound.
- Each wound needs a new gauze or sterile cotton swab.
- In principle, the skin area within 10 cm of the wound should be cleaned by the gauze and sterile cotton swab from up to down, and drop the used gauze and cotton swab into a zip bag.
- After cleaning the wound, the sterile cotton swab can be used to remove any discharge from the wound surface.
- Ointment may be applied to the wound, if indicated.
- When opening the bag with large gauzes and putting on another pair of clean gloves, you can hold the corner of the gauze and place the center of the gauze over the wound to cover it.
- Stick on the gauze with tape. Take off the gloves and drop them into the trashcan. At last, wash and clean your hands.
- If you are allergic to tape, you may use low-allergy tape or a bandage to manage the wound.

Observe the wound carefully; tell your doctor or other professionals and go to the clinic as soon as possible, if

- ✓ Redness is noted over the wound or around the wound.
- ✓ The yellowish and green discharge has a bad odor, or more discharge is noted from the wound.
- ✓ Bleeding is noted again, or cannot be stopped even with ten minutes of direct pressure.
- ✓ Swelling or pain is noted around the wound.
- ✓ The skin edge of the wound breaks down over 0.5 cm.
- ✓ The skin edge of the wound remains wet.
- ✓ Your body temperature is elevated over 38.5℃.
- ✓ You have any questions concerning wound condition and care.

Appendix 5-J Questionnaire Chinese version

個人基本資料

性別：☐女　　☐男　　**年齡（足歲）**：　　歲

身份：☐病友　　☐病友家屬或朋友

教育程度：☐未接受教育　☐國小　☐國中　☐高中　☐大專以上

請針對下列問題，分別選擇一個最適合的回答:

( ) 清創手術主要目的是為了？ (1)減輕疼痛 (2)檢驗感染細菌種類 (3)將傷口或其周圍的壞死組織、外來物質移除 (4)以上皆是

( ) 下列何者是清創手術之風險？ (1)可能會傷及血管、肌腱、神經等 (2)傷口表面的細菌可能在手術時進入深層組織中造成感染 (3)以上皆是

( ) 下列何者可能會增加清創手術之風險及術後的併發症？ (1)使用止痛藥 (2)使用類固醇藥物 (3)使用抗生素

( ) 下列何種情況較可能會增加清創手術之風險及術後的併發症？ (1)喝酒 (2)抽菸 (3)喝咖啡 (4)嚼檳榔

( ) 手術後應觀察傷口外觀，下列何者是正常現象？ (1)傷口周邊顏色呈現紅色 (2)流血或其他液體的滲出 (3)體溫 37℃ (4)傷口邊緣潮濕

( ) 冰敷應於手術後第幾天開始？ (1)1~3 天 (2)3~6 天 (3)6 天以上

( ) 冰敷的時間建議每次 (1)5~10 分鐘 (2)10~15 分鐘 (3)30~60 分鐘

( ) 下列何者並不是冰敷之作用？ (1)傷口止血 (2)促進血液循環 (3)減緩疼痛

( ) 熱敷應於手術後第幾天開始？ (1)第 1 天 (2)第 2 天 (3)第 3 天以後

( ) 更換紗布時，若紗布沾黏傷口，應如何處置？ (1)直接拉除 (2)在紗布上倒一些雙氧水 (3)在紗布上倒一些生理食鹽水或乾淨清潔液

我可以完全了解醫療人員對清創手術所提供的說明及資訊	非常不同意	不同意	普通	同意	非常同意
醫療人員所提供的資訊，可以協助我決定是否接受清創手術	非常不同意	不同意	普通	同意	非常同意
我對醫療人員的清創手術的說明過程很滿意	非常不同意	不同意	普通	同意	非常同意

Appendix 5-K Informed consent form Chinese version

清創手術說明同意書

這份說明書是有關您即將接受的手術效益、風險及替代方案的書面說明，可做為您與醫 師討論時的補充資料。最重要的是我們希望您能充份瞭解資料的內容，所以請仔細閱讀；如 果經醫師說明後您還有對這個手術的任何疑問，請在簽名前再與您的醫師充分討論，醫師會 很樂意為您解答，讓我們一起為了您及您的家人的健康努力。

手術前準備：

(1)手術前您會被要求穿上手術衣。
(2)接著您會被移至手術台，醫師會將手術區域及其周圍的毛髮清除並塗上消毒液。之後會在手術區域覆蓋上無菌單。
(3)然後進行麻醉工作。當麻醉生效後，醫師會在手術區域進行手術。

手術步驟：

(1)醫師會使用生理食鹽水將傷口之汙染物(如泥土、沙)沖洗乾淨。
(2)醫師會用手術鉗將傷口周圍組織拉起，再以剪刀或手術刀取下壞死的組織，此步驟會重複的進行，直到傷口清理乾淨為止。
(3)處置完成後會將肌肉層、其他組織縫合。
(4)縫合的時機，會視受傷原因、受傷位置、傷口感染可能性之高低而不同。一般在 6 小時至 5 天不等。
(5)在某些病例中，清創手術可能會重複的進行。
(6)表面皮膚會以縫線或 U 形釘閉合。最後覆上消毒紗布。

手術效益：(經由手術，您可能獲得以下所列的效益，但醫師並不能保證您獲得任何一項;且手術效益與風險性間的取捨，應由您決定。)

手術效益：清創手術是藉由外科方式將傷口或其周圍的壞死組織、外來物質移除的手術，是清理傷口時，最快也最有效率的方法；能阻止組織繼續壞死，避免傷口持續惡化，幫助肉芽、組織生長，促進傷口癒合。

清創手術說明同意書(承上頁)

手術風險及併發症：(沒有任何手術是完全沒有風險的，以下所列的風險已被認定，但是仍然可能有一些 醫師無法預期的風險未列出。)

手術風險及併發症：

(1)清創手術進行時，有可能會傷及深層的組織，如血管、肌腱、神經等。造成流血不止、肌腱損傷、神經損傷等併發症。

(2)傷口表面的細菌可能在手術進行時進入深層組織中造成感染。

(3)過去的疾病可能會增加手術的風險及術後可能的併發症。例如糖尿病、使用類固醇及其他免疫抑制藥物、免疫疾病等。

(4)抽菸、營養不佳、循環不佳也可能會增加手術的風險及術後可能的併發症。

(5)其他不可預知之突發性病變。

替代方案：(這個手術的替代方案如下，如果您決定不施行這個手術，可能會有危險，請與醫師討論您的決定)

可能替代方案：傷口處理可能有其他的方式可以進行，但不一定可行。如果您對於處置方式有所疑慮，請與您的醫師妥善討論其他方式的可行性及相關風險。

醫師補充說明：

本人(或家屬)_____已經與醫師討論過接受這個手術的效益、風險及替代方案， 本人對醫師的說明都已充分了解，並且保有此資料副本一份。

病患(或家屬)： (簽章)

與病人之關係：

見證人(本院醫護人員或病患家屬)： (簽章)

說明醫師： (簽章)

中 華 民 國 ： 年 月 日

Appendix 5-L Informed consent form English translation

Informed Consent for Surgical Debridement

The informed-consent document has been prepared to help inform you concerning the surgical procedure, benefits, risks, and alternatives, and will be a supplement when you discuss with your doctor. It is important that you read this information carefully and completely. If you have any question concerning the surgery, please feel free to discuss with your doctor. Your health is our only concern.

Pre-procedural preparation:

(1) You will be asked to put on the gown before the surgery proceeds.
(2) Then you will be moved to the operating table, and your doctor will remove hair and apply disinfectant on and around the surgical area. The surgical area will be covered by sterile drapes.
(3) Your doctor will perform the surgery after satisfactory anesthesia is done.

Procedure

(1) The surgeon will clean the wound and remove the contaminants as much as possible with normal saline.
(2) The surgeon may use surgical instruments to remove the necrotic tissue repeatedly until the wound is clean.
(3) When the procedure is finished, the surgeon will close the wound layer by layer.
(4) If the wound is not closed instantly, the wound will be cared for openly. The timing of wound closure will depend on the injured mechanism, the location of the wound, and the possibility of wound infection.
(5) In some case, the surgical debridement will be repeated.
(6) The skin will be closed by suture, adhesive tape, or staples, and covered by sterile gauge or dressing.

Benefits: (The benefits of the surgery are listed below, but none is guaranteed. You have to consider the benefits and risks carefully before making the decision.)

Benefits: Surgical debridement is the procedure to remove necrotic tissue and foreign bodies from wounds, and the fastest and most effective way to clean the wounds. It may prevent infection and improve the process of wound healing.

Informed Consent for Surgical Debridement(continue)

Risks and complications: (Every surgical procedure involves a certain amount of risk. The risk(s) listed below has/have been identified; however, some potential risks may not be included.)

Risks and complications:

(1) When the debridement is performed, deep tissue such as vessels, tendons, or nerves might be injured, and the complications will include bleeding, tendon injury, nerve injury, postoperative range of motion limitation of limbs, wound pain, or permanent scarring, etc.

(2) Bacteria over the skin might affect the deep tissue and cause infection, and the rate of infection might differ and depend on the cause of injury, mechanism, and location of the wound.

(3) Past illness might increase the risks of the procedure and postoperative complications, such as Diabetes Mellitus, using steroid and anti-immune drugs, anti-coagulants, and immune-compromised diseases.

(4) Smoking, poor nutrition, or poor circulation might increase the risks of the procedure and postoperative complications.

(5) Unforeseen disorders might occur, such as shock, or arrhythmia.

Alternatives: (The possible alternative form(s) is/are listed below. It may be risky, if you choose not to receive the surgery. Please discuss with your doctor about your decision.)

Possible alternative forms: Wound management might be performed in other ways, such as a bio-artificial dressing might be used to debride the wound, but it takes 2~4 weeks, and has the increased risk of wound infection. If you have any questions concerning the treatment, please discuss these with your physician.

Additional recommendations:

I (or family member)_____ have read and understood the following Informed Consent Material for my specific procedure. The risks, benefits, and alternatives of the procedure(s) was/were explained to me. I have a copy for this document.

Patient (or family member)： (sign)

Relationship with patient：

Witness (medical staff or family member)： (sign)

Physician： (sign)

Appendix 5-M Wound care Chinese version

傷口照護

一、注意事項

所有創傷傷口皆有感染之可能，請務必保持清潔。

二、我該怎樣照護自己？

1. 受傷之第一天至第三天請為傷口進行冰敷,建議每天執行三至四次，每次十至十五分鐘。冰敷可讓傷口止血，減少腫脹：亦可減緩疼痛感。
2. 受傷第三天以後，建議為傷口熱敷，熱敷能促進血液循環，可以消除傷口之腫脹。

三、我應該如何換藥？

所有創傷傷口建議在第二天開始換藥。建議使用乾淨的清潔液或市售之外用生理食鹽水清洗傷口。

照顧傷口時需要：(1) 2 雙乾淨的拋棄式手套 (2) 生理食鹽水或乾淨清潔液 (3) 清潔傷口用的小塊紗布 (4) 包紮傷口用的大塊紗布 (5) 透氣膠布。

換藥步驟：

1. 仔細洗淨及擦乾雙手。帶上手套。
2. 先移除傷口上的包紮紗布。若紗布與傷口沾黏，在紗布上倒一些生理食鹽水或乾淨清潔液。之後再輕輕將紗布取下。

3. 將清潔液倒在小紗布上。將紗布由傷口的上方往下或由內往外清潔，清潔完畢後將紗布丟入封口袋。

4. 原則上，傷口周圍 10 公分的皮膚都要以紗布清潔。清潔後，以無菌棉棒拭除傷口表面之分泌物即可。

5. 必要時，再將傷口塗抹上藥膏。

6. 清洗並擦乾手。穿上另一雙乾淨的手套雙手握在紗布對角的角落上。

7. 將紗布的中心放置在傷口上。以透氣膠布將紗布牢牢黏貼住。

8. 脫去手套，清洗並擦乾手。

9. 若皮膚對透氣交部過敏,可以在藥房購買低敏感膠布或使用繃帶包紮傷口。

四、 如果有下列情形，請立刻回來複診

- 傷口或周圍皮膚呈現紅色。
- 傷口滲出之液體呈現黃色且有異味。
- 傷口再度出血，經直接加壓十分鐘以上仍無法止血者。
- 傷口周圍皮膚腫脹。
- 經縫合的傷口其邊緣裂開。
- 傷口邊緣潮濕。

體溫升高，超過 38.5℃。

Appendix 5-N Wound care English translation

Wound care

A. Precautions

There are infection risks for all traumatic wounds. Please remain wounds clean.

B. How do I take care of myself?

1. Ice packing over the wound is recommended during one to three days after injury, and it can be done ten to fifteen minutes for three to four times per day. Ice packing might stop the bleeding and alleviate the swelling as well as pain of the wound.
2. Hot packing is recommended after 3 days of injury to improve the circulation alleviating the swelling of wounds.

C. How should I change dressings?

Dressing change is suggested on the second day after injury for wounds. Normal saline can be used to clean the wound.

For wound care, you may need:

- Two clean disposable gloves
- Normal saline
- Small gauze or sterile cotton swab to clean the wound
- Large gauze to cover the wound
- Adhesive tape

The procedures of changing the dressing:

1. Clean and wash your hands first, and put on the clean gloves.
2. Then take off the covered gauze from the wound. If the gauze adheres to the wound, normal saline might be used to rinse the gauze, and then the gauze might be removed gently a few minutes later.
3. You may use normal saline to rinse small gauze. The wound can be cleaned by small gauze from up to down or from in to out circularly, and the gauze and sterile cotton swab should be dropped into a zip bag after cleaning the wound.
4. In principle, the skin area within 10 cm of the wound should be cleaned. After cleaning the wound, the sterile cotton swab can be used to remove any discharge from the wound surface.
5. Ointment may be applied to the wound, if indicated.
6. When opening the bag with large gauzes and putting on another pair of clean gloves
7. You can hold the corner of the gauze and place the center of the gauze over the wound to cover it. Stick on the gauze with tape.
8. Take off the gloves. At last, wash and clean your hands.
9. If you are allergic to tape, you may use low-allergy tape or a bandage to manage the wound.

◆ Observe the wound carefully; tell your doctor or other professionals and go to the clinic as soon as possible, if

- ✓ Redness is noted over the wound or around the wound.
- ✓ The yellowish and green discharge has a bad odor, or more discharge is noted from the wound.
- ✓ Bleeding is noted again, or cannot be stopped even with ten minutes of direct pressure.
- ✓ Swelling or pain is noted around the wound.
- ✓ The skin edge of the wound breaks down over 0.5 cm.
- ✓ The skin edge of the wound remains wet.
- ✓ Your body temperature is elevated over 38.5℃.
- ✓ You have any questions concerning wound condition and care.

CHAPTER SIX

Manuscript Three

An intervention for improving the informed consent process in trauma patients undergoing the surgery of debridement

Abstract

Objective

This study is an attempt to determine whether educational videos are superior to conventional discussion for informing trauma patients undergoing surgeries about the procedure, benefits, risks, alternatives, and postoperative care.

Methods

Audiovisual videos including information about the procedure, benefits, risks, alternatives, and postoperative care for the surgery of debridement were developed and applied. A prospective randomized controlled trial was conducted, and all trauma patients meeting the study interest scheduled to receive the surgery of debridement in the emergency department were included. Patients were assigned to the video group, in which patients watched an educational video illustrating the surgery of debridement, in terms of the procedure and its benefits, risks, alternatives, and postoperative care, or to the control group, in which patients had conventional discussion and received information from their surgeon. A knowledge test and questions evaluating satisfaction with the process of informed consent were completed by the participants after their educational sessions. Primary outcomes were to evaluate whether the educational videos were superior to conventional discussion for informing patients. Secondary outcomes were compared to access the patients' satisfactions and refusals to sign consent.

Results

A total of 185 adult patients were solicited to participate during the seven-month study period. One hundred and forty-nine of the 185 patients were enrolled in the study when research associates were available. Of these, one declined and six were excluded owing to clinical instability. One hundred and forty-two patients were enrolled, and 70 were assigned to the video group and 72 to the control group. Mean scores of knowledge test were higher in the video group in comparison with conventional discussion. Patients in the video group had greater satisfaction than patients in the conventional discussion group. No patient refused to sign consent to

receive the surgery of debridement.

Conclusions

Using educational videos is a good tool for improving informed consent process for surgery in trauma patients. Video-assisted informed consent may improve patient understanding of the surgery and satisfaction with the process of informed consent in trauma patients undergoing the surgery of debridement. Future studies are recommended to accord with the results of these precursory findings and explored among trauma patients with different types of injuries and severities.

Background

Informed consent is not a document, but rather a process.[1-6] It is ethical, imperative, and legally essential for physicians to provide information concerning invasive procedures, including the risks, benefits, and alternatives during the informed consent process.[7-11] It is crucial for patients to have sufficient knowledge about the process and risks of the procedure to consent any medical procedure. Only when patients understand this information may it facilitate making individual choice.[12-15]

Trauma is one of the leading causes of death and disability and one of the top leading death for children and young adults in both developed and developing countries. It is a major public health problem in the world. [16] Obtaining valid informed consent for trauma patients in the emergency department is a challenging and time-consuming process. Because of the involuntary nature of emergency care, informed consent is the only way to respect patients' autonomy.[17, 18] As for most situations occurring in emergency settings, time constraint and stress as well as the distress by other acute symptoms or pain in patients, patients and their families often have difficulty in absorbing and understanding the significant information needed to give consent.[18-26] Therefore, a cooperative effort made by the healthcare providers should generate the most effective way to transport information, which may facilitate patients and family members to make rational decisions even under these most demanding conditions.

Nevertheless, during the traditional consenting process, investigators have found trauma patients have difficulty in retaining the vast load of information presented to them on the one hand, and patients often could not imagine how the surgery would take place on the other. Therefore, a practical solution may involve using educational videos to assist the informed consent process for the surgery. Furthermore, the use of an educational video to assist a preoperative discussion may improve patient satisfaction and make the most of information gain.[9, 27-29] Several studies have also shown that videos for educating patients procured better patient satisfaction and improved patient knowledge concerning the procedures and risks. [27, 30-33]

Although clinical studies in other medical areas have shown that video-informed patients retain a larger amount of information, the use of video information for trauma patients in the emergency department has never previously been studied. Therefore, the investigators wished to address this issue with the addition of a video-assisted informed consent process. To our knowledge, using educational videos to improve the informed consent process for trauma patients in the emergency departments has never been studied.

This study planned to determine whether educational videos were superior to conventional discussion for informing trauma patients undergoing the surgery of debridement about the procedure, benefits, risks, alternatives, and postoperative care.

Methods

Intervention tool

The audiovisual videos had been designed and developed in another study. The final videos included information about the procedure, benefits, risks, alternatives, and postoperative care of the surgery of debridement. A questionnaire with knowledge test concerning benefits, risks, alternatives, and postoperative care had also been developed and tested.

The video for the surgery of debridement was developed using advanced 2-dimensional (2-D) graphics technology. The video included seven sections, including “Choose the Appropriate Procedure”, “Medical History”, “Anesthesia”, “the Procedure, Benefits, and Risks”, “Alternatives”, “Postoperative Recovery”, and “Wound Care”.

One portable computer preloaded with the video was used. The volume was adjusted to ensure that participants could hear the narrative. A research associate provided assistance as needed when participants watched the video and made sure participants completed the process without questions. Watching the video took approximately 15 minutes, after which time the healthcare provider provided an opportunity for participants to ask questions if participants had any questions about the surgery of debridement.

Study design

The study conducted a prospective randomized controlled trial. Patients were enrolled on a sample of adult trauma patients scheduled to receive the surgery of debridement for complicated wounds over limbs in the emergency department of Kaohsiung Medical University Hospital. Wounds over face were excluded because of cosmetic concern. Wounds involving tendon rupture or nerve injury were also excluded because of different rehabilitation program postoperatively. Patients who were randomized to the intervention group watched a video illustrating the surgical procedure and its benefits, risks, alternatives, and postoperative care. The control group underwent routine discussion, receiving information for the surgery of

debridement from their healthcare provider, and then viewed information about the surgery of debridement from the extended consent form. Patients in the intervention group viewed the video at their bedside on a portable computer. In our hospital, a written consent form with specific information for the surgery is provided for patients to read and sign. The extended consent form had been developed and had similar information to the video. It ensured that the same quality of information was delivered to the patients. Before and after their informed consent process, all participants were asked to complete a knowledge measure. Questions using the 5-point Likert scale were asked to evaluate the satisfaction with the informed consent process after the educational sessions. In our emergency department, senior resident and chief residents were the responsible healthcare providers for obtaining informed consent for the surgery. Residents obtaining the informed consent were blinded to the knowledge measure.

Research associates approached the eligible patients by using a prescribed method to explain the study and obtained written informed consent for the study if patients agreed to participate. Patients who agreed to participate were randomized to the video (intervention) group, or the routine informed consent (control) group. The group allocation was performed by simple randomization based on the generated number, odd or even, through a computer-based random number generator in a concealed manner. After randomization, participants were interviewed to collect their demographic information, including age, gender, and level of education. Other variables, including injury severity score, being transferred, arrived time, and physician consultants, were collected from charts and our computer system.

In the control group, the participants were asked to complete a knowledge measure as a baseline measure. And then, participants were provided a written consent form containing the information about the surgery of debridement for participants to read and sign. The participants were provided with an educational session to discuss their concerns and questions with their healthcare provider. At last, the participants were asked to complete a knowledge measure after the educational

session. Questions evaluating their satisfaction with the informed consent process were also asked after the educational session.

In the intervention group, the participants were also asked to complete a knowledge measure before the educational session. Then, participants were provided an educational video illustrating the procedure, risks, benefits, alternatives, and postoperative care about the surgery of debridement to watch. If patients had any further questions about the surgery, participants had the opportunity to speak with their healthcare provider after the video education session. This question-and-answer session created the same opportunity as the control group, in which participants might ask questions during conventional informed consent. The same knowledge test and satisfaction measures were evaluated for patients in the intervention group as patients in the control group after the question-and-answer session.

A research associate assisted in reading the questions and checked the patient's responses on the questionnaire, if patients requested that the questions be responded to orally. Research associates were trained and read the questions in a neutral pattern to avoid interviewer bias. If the questions were responded to orally, this was also recorded in the log book.

Participants

Adult trauma patients undergoing the surgery of debridement for study interest were eligible for enrollment, if the trained research associate was available. To give sufficient power to the study, one hundred and thirty-six patients were predetermined as target sample size. The research associates approached the participant and collected relevant data during the study period. Patients who were clinically unstable, refused to participate, or were unable to speak Mandarin or comprehend the process for this study were excluded. Due to the uncertainty of trauma injury, eligible cases were missed if research associates were not available. If an eligible patient was missed, the missed case and the reason would be recorded in the log book. The research associates watched surgical scheduling of operation rooms from the hospital computer system to identify eligible cases, and were trained for the study interest.

Data process and statistical analysis

The primary outcome was determined by quantitative scores from 0% to 100%, representing patient understanding of the procedure, benefits, risks, alternatives, and postoperative care. Questions were multiple-choice formats, and the quantitative scores on the written test were calculated. Secondary outcomes were evaluated by a five-point Likert ordinal satisfaction scale, representing patient satisfaction with the informed consent process. The frequency of refusal to sign consent was also recorded.

Data collected from participants were recorded by participant number, without any specific identification to the participant. This method may protect patient privacy and secure patient confidentiality. Descriptive statistics were used to analyze the baseline characteristics of the control and intervention groups. Mean and standard deviations were calculated for continuous variables if normally distributed, and proportions were calculated for categorical variables. The Fisher exact test was conducted for binary, ordinal, and categorical variables. Mean scores on the knowledge measure before and after the educational sessions were compared using Student's *t*-test between each group and paired *t*-test within each group. Independent factors found to be associated with the difference of knowledge score and patient satisfaction by univariate analysis were subsequently entered into multivariable regression models. A multiple linear regression model of the difference of knowledge score with predefined covariates was performed. For patient satisfaction, the investigators further categorized the five-point Likert scale into two categories of "strongly agree" and "others". A multivariable logistic regression model of patient satisfaction with predefined covariates was performed, and likelihood ratio tests for the multivariable models were performed. All data analysis was performed with the Stata version 10.0 (StataCorp, College Station, TX).

Results

A total of 185 adult patients were scheduled to receive the surgery of debridement during the study period. (Figure 6.1) A research associate was available to enroll 149 of the 185 patients. Of these, one declined and six were excluded owing to being clinically unstable. Reason for non-participation was being “too nervous”. Data was thus presented for 142 subjects in Table 6.1. There were 72 participants in the control group and 70 participants in the intervention group. There were no important differences for age, gender, level of education, injury severity score, being transferred, arrived time, and physician consultants between control and intervention groups.

The knowledge measurement

Table 6.2, Table 6.3, and Figure 6.2 summarize the main outcomes for all study participants. Individual performance on the knowledge test between the two groups showed that patients had no significant differences on baseline knowledge score between the two groups, and there was greater understanding after education in the intervention group in comparison with the control group (mean knowledge scores 77.06 versus 65.18 respectively). Participants had higher knowledge scores after education in comparison with those at baseline in the two groups. There was statistically significant difference in the difference of knowledge score between two groups, and the improvement in the knowledge score was higher in the intervention group (mean difference of knowledge scores 18.71) than the control group (mean difference of knowledge scores 10.83).

Table 6.4 shows baseline knowledge score in different subgroups in terms of age, gender, level of education, injury severity score, being transferred, arrived time, and physician consultants between control and intervention groups. There was no significant statistical difference on these measures between control and intervention groups.

Table 6.5 shows post-education knowledge scores in different subgroups in terms of age, gender, level of education, injury severity score, being transferred, arrived

time, and physician consultants between control and intervention groups. For those patients whose age was less than 36, the post-education knowledge score was significantly higher in the intervention group than the control group. There was no statistically significant difference for those patients whose age was equal to and greater than 36 between control and intervention groups. Male patients had statistically significantly higher scores in the intervention group than control group. However, female patients had higher scores in the intervention group but there was no statistical significance compared to the control group. Those patients whose level of formal education whether below or above high school had statistically significant higher post-video educational scores in the intervention group compared to the control group. For those patients whose injury severity score was equal to and less than 4, the post-education knowledge score was significantly higher in the intervention group than control group. There was no statistically significant difference for those patients whose injury severity scores were greater than 4 between control and intervention groups. Those patients transferred from other hospitals had statistically significant higher post-educational scores in the intervention group compared to the control group. No matter whether patients arrived in the emergency department between 8am and 4pm or at other times, there were statistically significant higher post-educational scores in the intervention group compared to the control group. No matter who the physician consultant was, there was no significant difference for post-educational score between intervention and control groups.

Table 6.6 shows the difference of knowledge score in the subgroups in terms of age, gender, level of education injury severity score, being transferred, arrived time, and physician consultants between control and intervention groups. The difference of knowledge score is statistically significantly greater in the subgroups of age less than 36, male, level of education above high school, and injury severity score equal to and less than 4 in the intervention group compared to the control group. Though there was no statistical significance, patients whose level of education was below high school had greater difference of knowledge scores for the intervention group compared to the

control group. Those patients transferred from other hospitals or not, had statistically significant greater differences of knowledge scores in the intervention group compared to the control group. No matter whether patients arrived in the emergency department between 8am and 4pm or at other times, there were statistically significant higher differences of knowledge scores in the intervention group compared to the control group. No matter who the physician consultant was, there was no significant difference for the difference of knowledge scores between the intervention group and control group.

Multiple linear regression model was applied to study the adjusted impact of video education controlling for predefined covariates, such as age, gender, level of education, injury severity score, being transferred, arrived time, physician consultant, and baseline knowledge score. The results revealed that video education significantly increased the difference of knowledge score, controlling for these other influences. The average difference of knowledge was increased by 7.646 points. Moreover, age, injury severity score, and baseline knowledge score also had significant influences on the difference of knowledge score, controlling for other covariates. The coefficients were -0.161, -0.842, and -.0379 respectively.

Patient satisfaction

Patient satisfaction as measured on a 5-point scale is listed in Table 6.8. There were statistically significant differences between control and intervention groups on “I can comprehend the information that healthcare providers provided for the surgery”, “The information that healthcare providers provided can help me make decision for the surgery”, and “I am satisfied with the informed consent process for the surgery”. No patient in either group refused to sign consent for the surgery.

For patient satisfaction, the investigators further categorized the five-point Likert scale into two categories of “strongly agree” and “others”. Table 6.9 shows the results of subgroup analysis of satisfaction for “I can comprehend the information that healthcare providers provided for the surgery” between control and intervention groups. Those patients, whose age less than 36, level of education equal to or higher

than high school, injury severity score less than 4, and physician A, had the higher statistically significant percentage of rating “strongly agree” in the intervention group than control group. No matter whether patients were female or male, transferred or not, arrival time in the emergency department, and their baseline knowledge scores, patients had higher statistically significant percentages of rating “strongly agree” in the intervention group than the control group. Patients with higher differences of knowledge score had higher statistically significant percentages of rating “strongly agree” in the intervention group than control group.

Table 6.10 shows the results of subgroup analysis of satisfaction for “The information that healthcare providers provided can help me make a decision for the surgery” between control and intervention groups. Those patients, whose level of education below high school, injury severity score greater than 4, being transferred, and not treated by physician A, had no statistically significant higher percentage of rating “strongly agree” in the intervention group compared to the control group. Other subgroups had statistically significant higher percentages of rating “strongly agree” in intervention group compared to the control group. Patients with higher difference of knowledge scores had higher statistically significant percentages of rating “strongly agree” in the intervention group than the control group.

Table 6.11 shows the results of the subgroup analysis of the satisfaction for “I am satisfied with the informed consent process for the surgery” between control and intervention groups. For those patients, whose age was equal to or greater than 36, were female, whose level of education was below high school, had injury severity score greater than 4, and were not treated by physician A, had no statistically significant higher percentage of rating “strongly agree” in the intervention group compared to the control group. Patients in other subgroups rated more “strongly agree” satisfaction with their informed consent process for the surgery in the intervention group compared to the control group. Patients with higher differences of knowledge score had higher statistically significant percentages of rating “strongly agree” in the intervention group than in the control group.

Multivariable logistic regression models of patient satisfaction controlling for predefined covariates, such as such as age, gender, level of education, injury severity score, being transferred, arrived time, physician consultant, and baseline knowledge score, are presented in Table 6.12. The adjusted odds ratio for the intervention group suggests that the intervention improved patient perceptions of satisfaction. Adjusted odds ratio for "I can comprehend the information that healthcare providers provided for the surgery", "The information that healthcare providers provided can help me make decision for the surgery", and "I am satisfied with the informed consent process for the surgery" was 3.299 (95% confidence interval 1.614 to 6.746), 3.246 (95% confidence interval 1.567 to 6.727), and 3.702 (95% confidence interval 1.747 to 7.843) respectively.

Discussion

Our results indicate that higher knowledge scores were yielded in trauma patients by using educational videos for the informed consent process of the surgery of debridement. In our sample, patients had greater satisfaction for the informed consent process in the video group in comparison with the conventional discussion group. To our knowledge, this is the first study to use educational videos to improve the informed consent process for trauma patients in the emergency department.

The results of the study showed that trauma patients had better understanding about the information provided by the video compared with that obtained from the traditional informed consent process. Traditional information delivery about treatments is usually transferred by oral or/and written ways. However, studies revealed that patients might have poor understanding of information presented to them using the traditional ways. [34-38] Patient factors (age, level of education, previous experience, conscious level, etc.), physician factors (years in practice, communication skill, use of information aids, etc.), and injury context (injury type, severity of injury, etc.) may affect information exchange, patient's deliberation and voluntarism to making treatment decision and provide consent.[39, 40] Many other conditions may also have an influence on patient's understanding, such as illness, irrationality, and immaturity.[7] In our study, the investigators had found that young age, injury severity, baseline knowledge score, and the use of educational video were significant factors predicting patient's knowledge and understanding. Further studies are needed to confirm these results.

Understanding as other elements is one of the important elements for informed consent. The healthcare providers have to disclose information to patients, and patients have to understand what information physicians provide to them to make an autonomous decision. However, "understanding for surgical patients is poor." [41] The investigator believed this problem would be more aggravated for trauma patients. Trauma patients with physical pain and emotional stress under an environment of time constraint in the emergency settings usually have difficulty in understanding the

information presented to them. It is vital that healthcare providers convey any complicated treatment information to the patients, and patients need to have adequate knowledge about the treatment to facilitate individual choice.

Moreover, many medical terms may possibly confuse patient's understanding. Sometimes, the same word may mean something different to physicians and patients. Cainzos and Gonzalez-Vinagre recommended that the design of the informed consent document is very important. Technical terms and long sentences should be avoided so as the documents are easy to read and understand. [42] Therefore, physicians must try their best to use those words that patients can understand and consider the patient's medical condition to ensure their best understanding. The authors also recommended that assessing the patient's understanding of the presented information is an important part of the surgeon's responsibility.

Furthermore, Kusec et al studied how to improve the understanding for informed consent and recommended that it is important to involve patients to participate in the development of informed consent information as well as to devote the method for developing educational materials for improving understanding. The authors also concluded that an easier style and some variables such as educational level should be considered when surgical information is delivered. [43]

Nehme et al studied on the effect of the use of multimedia consent programs for surgical procedures. The authors reviewed 33 articles and reported that it was difficult to conclude whether higher patient satisfaction was correlated with improved understanding or merely with the use of multimedia program.[44] In our study, our results revealed that the use of the educational video might improve patients' knowledge and satisfaction. The improvement of the knowledge was associated with the higher patient satisfaction. The results may reflect that the usage of the educational video itself may improve patient satisfaction as well as the improvement of patients' knowledge may do.

Our results revealed patients had relatively limited improvement on mean knowledge scores in both groups. One of the reasons for this may echo an intrinsic

difficulty with obtaining valid informed consent from trauma patients. A previous study revealed that patients may have poor understanding of study goals, risks, and benefits, when patients are under acute medical conditions.[45] Another reason resulting in this problem may be because of the constrained time required for patients to absorb the complicated information needed to provide valid informed consent, especially in trauma patients.

Time may have an influence on patient's deliberation.[46] Theoretically, if patients had more time to approach provided information and deliberate, they might have better understandings. Fink et al reported that factors predicting patient's understanding during surgical informed consent included age, ethnicity, lower level of education, operation type, the use of repeat back, and total consent time.[47] The authors also revealed that it was limited for understanding during informed consent discussions in individuals with potential language difficulty due to ethnicity or education. Therefore, the authors recommended that providing adequate time and using informed consent adjuncts for informed consent discussions may improve patients' understanding. Some authors also reported that patients with lower educational level may improve their understanding from additional intervention.[41] In our study, though the investigators did not evaluate the time spent on each participant, the investigators believe that the needed time for each participant to complete the consent process should be similar in the intervention and control groups. The investigators provided the similar time for participants to read the written information or watch the video and provide similar time for participants to ask questions. The time issue might not have an influence on the result of our study.

Furthermore, patients with lower education level though had greater difference of knowledge score in the intervention group compared to the control group in our study, but no statistical significance was found. Moreover, there was no higher satisfaction for satisfaction survey. In our opinion, the audiovisual education video might be expected to have more benefit for patients whose level of education is lower, since those patients might have the difficulty in reading, and the visual information

might be helpful for them to understand what the important information is. There might be several reasons for these results. The sample size for lower education level was small in our study, and the results might not reflect the whole picture. Second, the video design might be not suited for those patients. The ways of video layout and the narrative expression might have an influence on patient's understanding and satisfaction. Further researches are needed to explore this association.

In our study, the investigators had found that different information aid might have different influences on patient's understanding and satisfaction for informed consent. The educational video had increased the post-education knowledge score and the difference of knowledge score as well as patient satisfaction. Furthermore, the investigators had found that younger and male populations have greater impact from video education upon their understanding. It revealed that different patient populations might have different preference for information aid provided on their learning. Though the educational video might increase patient's understandings and satisfaction in general, however, a tailor-made information aid might be needed for patients to improve their understandings and satisfaction. Further researches are needed to confirm the effectiveness.

Except for the content of the video, it is believed that the production of the video has an influence on patient's understandings and satisfaction. If the video is produced attractively, the effect of education might be better. Actor role-play, 2D (2-dimensional) or 3D (3-dimensional) graphics, or interactive computer program could be considered to display the video, and their effects on patient's outcome might be different. Moreover, in our opinion, the audio narratives have also an influence on patient's absorption of information. The female voice may sound soft, and the male voice may sound authoritative. The effectiveness of the information delivery might be different. Further researches are needed to explore these associations and effects.

Furthermore, the use of video to communicate does not allow instant questions and answers. Also, there might not be a chance for patients to repeat or focus on the specific part of what they are concerned of. An interactive program with tailor-made

design would be perfect for this purpose. Moreover, it still must be emphasized that such information aids should not replace the entire process of informed consent. Patients should have a chance to communicate with their healthcare providers. Informed consent is a crucial process in which patients and healthcare providers have a good opportunity to express their own opinions and values, exchange information, and make themselves mutually understood.

The documentation is another issue for informed consent electronically. It is worthy of consideration about how to preserve the appropriate document of consent for the requirement of regulations and laws in the institutions. Some authors have reported the experience for electronic consent, and the electronic signature had been integrated into patient's electronic record.[48]. Future study is needed to approve its applicability and effectiveness.

Therefore, the importance of the effectiveness and efficiency of preoperative education and communication process as well as the entire consent process during emergency surgery should never be underestimated. It is believed that a good consent process will dramatically increase the satisfaction of trauma patients during emergency surgery. The education aids and supportive materials are important for the informed consent process, but the way how to deliver the information is also essential.[49] Hence, to obtain informed consent effectively and efficiently, a comprehensive tool and a standardized consent process should be developed in emergency settings for trauma patients and their families.

Though the video succeeded in improving patient knowledge and satisfaction for the informed consent process in trauma patients, it should be emphasized that major improvement was achieved by the institution devoting its efforts to improve patient safety and quality of care through conveying structured information and standardizing the process for trauma patients in the emergency department. The investigators believe that the improvement in patient outcomes has reflected these achievements. Institutions, on one hand, should emphasize patient-centered health care as a top priority, and on the other, should attach importance to improve quality of care for

trauma patients in the emergency department. Emergency department staff must often share this value with other staff and healthcare personnel to provide appropriate care for the trauma patient during any part of their care.

Moreover, the investigators believe that the structured and standardized informed consent process might promote patient's understandings and satisfaction, even build a good relationship between patients and healthcare providers. However, in the litigious world, whether the effort has the effect on decreasing complaints or even lawsuit for a long run needs further researches to explore the impact.

The study has limitations. Though our study revealed promising results, the study is based on one pilot study and at an exploratory stage aiming for a viable alternate to current practice. It represents only one specific surgery conducted at one institution, and the results may not be generalized to other surgeries or institutions. The study did not evaluate the effect of the educational video on patient's anxiety. In our opinions, the level of anxiety might be higher for trauma patients in the emergency department, and the educational video should have the effect of eliminating some degree of anxiety for trauma patients. Further researches are needed to confirm this effectiveness. In our study, the information retention has not been evaluated. Further researches are recommended to explore the effectiveness of an educational video on the information retention and patient satisfaction for trauma patients. Moreover, the video in this study did not prepare different versions each using a different dialect native to the patient's mother-tongue. Different versions of video with different languages should be prepared and studied for their effectiveness.

However, the study has several strengths. Randomization may balance patient background and knowledge of the surgery between each group. Baseline knowledge measure was formally tested and may limit some potential bias (such as healthcare provider factors or patients' previous exposure to the surgery, etc.) that may have an influence on post-education measures to reflect the actual improvement of the intervention. Moreover, the study has several important elements that have never been

studied before, including the usage of the video containing the informed consent information for trauma surgery and study population in the emergency setting.

Conclusions

In summary, using educational videos is a good tool for improving the informed consent process for the surgery of debridement in trauma patients. Video-assisted informed consent may improve patient understanding of the surgery of debridement and satisfaction with the process of informed consent in trauma patients. Future studies are recommended to accord with the results of these precursory findings and explored among patients with different types of injuries and severities.

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Figure 6.1 Profile of randomized controlled trial. *RA,* Research associate.

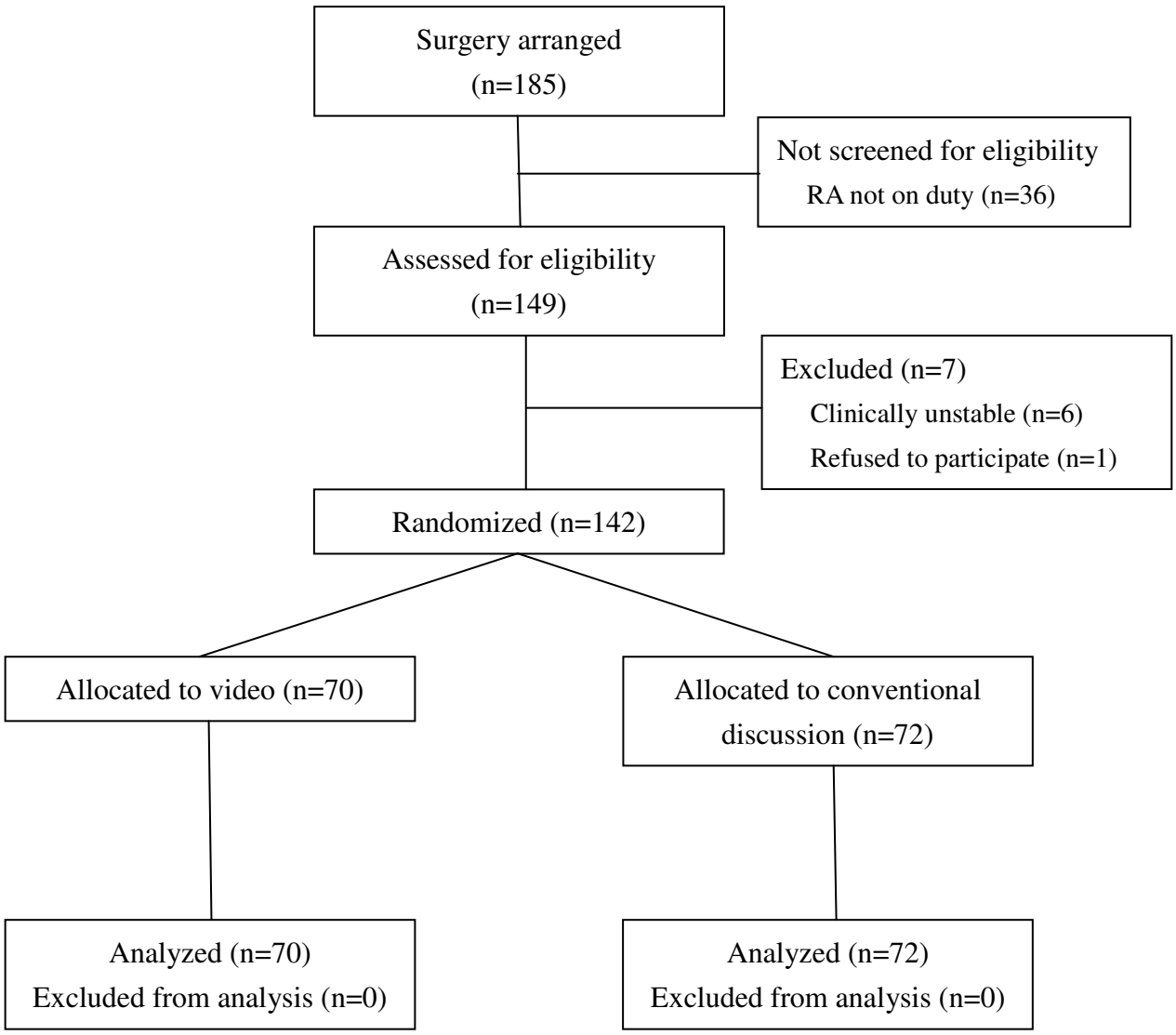


Table 6.1 Baseline characteristics

Characteristic	Control (n=72)	Intervention (n=70)	p-value
Age, No (%)			0.249
<20	2 (2.8)	9 (12.9)	
20–29	23 (31.9)	25 (35.7)	
30–39	17 (23.6)	9 (12.9)	
40–49	12 (16.7)	12 (17.1)	
50–59	13 (18.1)	10 (14.3)	
60–69	2 (2.8)	3 (4.3)	
>69	3 (4.2)	2 (2.9)	
Male, No (%)	43 (59.7)	36 (51.4)	0.398
Education, No (%)			0.565
<High school	13 (18.1)	8 (11.4)	
High school	26 (36.1)	27 (38.6)	
College	33 (45.8)	35 (50.0)	
Injury severity Score >4, No (%)	17 (23.6)	13(18.6)	0.539
Transferred, No (%)	16(22.2)	19(27.1)	0.561
Arrived time, 8-16 h, No (%)	30(41.7)	36(51.4)	0.313
Physician, No (%)			0.423
Physician A	18(25.0)	16(22.9)	
Physician B	7(9.7)	10(14.3)	
Physician C	14(19.4)	6(8.6)	
Physician D	11(15.3)	12(17.1)	
Physician E	9(12.5)	14(20.0)	
Physician F	13(18.1)	12(17.1)	

Abbreviation: ED, emergency department;

Table 6.2 Comparison of baseline and post-education knowledge scores between control and intervention groups

Knowledge score	Control (n=72)		Intervention (n=70)		p-value
	Mean	Standard Deviation	Mean	Standard Deviation	
Baseline	50.83	18.67	53.86	16.44	0.308
Post-education	61.67	18.39	72.57	16.21	<0.001
Difference of knowledge score	10.83	11.23	18.71	16.76	0.001[a]

[a] Unequal variance test

Table 6.3 Comparison of knowledge scores of control and intervention groups between baseline and post-education status

Group	Baseline		Post-education		p-value
	Mean	Standard Deviation	Mean	Standard Deviation	
Control (n=72)	50.83	18.67	61.67	18.39	<0.001
Intervention (n=70)	53.86	16.44	72.57	16.21	<0.001

Figure 6.2 Baseline and post-education knowledge scores in control and intervention groups

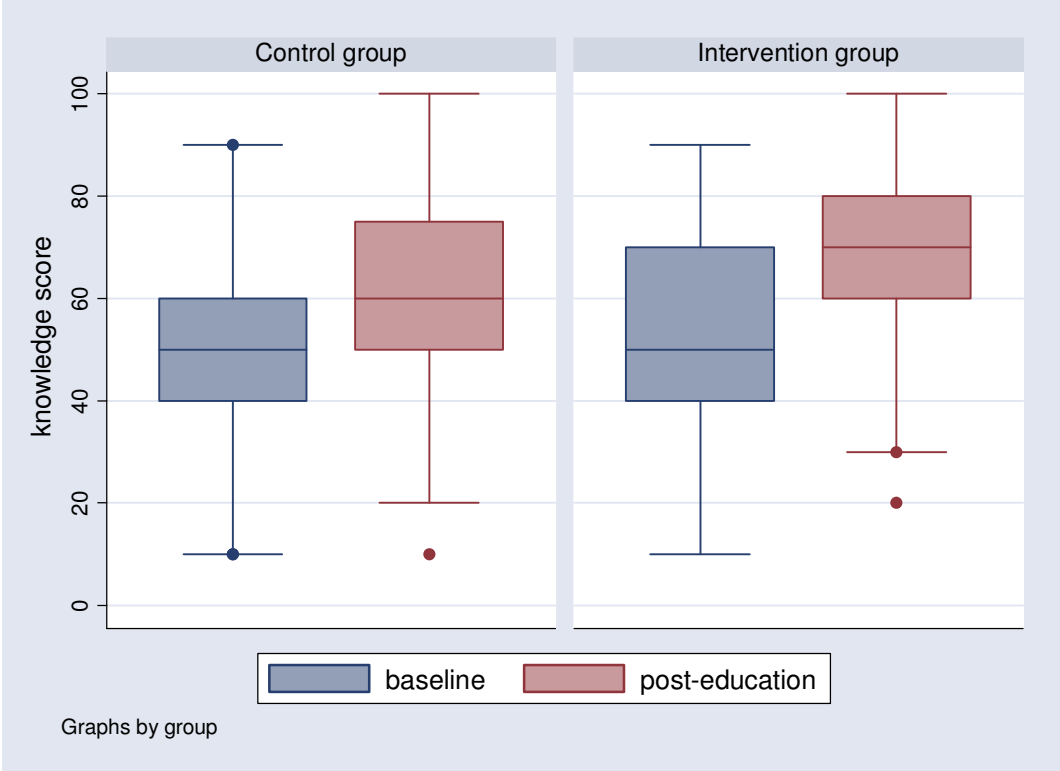


Table 6.4 Baseline knowledge score between control and intervention subgroups.

Variable	Control			Intervention			p-value
	No.	Mean	Standard deviation	No.	Mean	Standard deviation	
Age							
<36	32	55.94	17.01	39	56.41	17.09	0.908
≥36	40	46.75	19.13	31	50.65	15.26	0.357
Gender							
Female	29	56.90	16.93	34	56.47	17.73	0.923
Male	43	46.74	18.86	36	51.39	14.96	0.236
Education							
<High school	13	35.39	19.42	8	46.25	9.16	0.157
≥High school	59	54.24	16.84	62	54.84	16.96	0.845
Injury severity Score							
≦4	55	51.09	18.82	57	54.04	16.89	0.385
>4	17	50.00	18.71	13	53.08	14.94	0.631
Transferred							
Yes	16	52.50	20.49	19	55.26	14.67	0.646
No	56	50.36	18.29	51	53.33	17.17	0.389
Arrived time							
8-16 h	30	49.00	16.47	36	51.67	16.30	0.513
Others	42	52.14	20.19	34	56.18	16.52	0.351
Physician							
Physician A	18	56.67	16.80	16	52.50	14.38	0.446
Physician B	7	47.14	19.76	10	56.00	18.97	0.366
Physician C	14	47.86	19.29	6	53.33	21.60	0.581
Physician D	11	45.46	22.07	12	60.00	15.37	0.079
Physician E	9	52.22	17.87	14	50.00	20.00	0.789
Physician F	13	51.54	18.64	12	52.50	11.38	0.879

Abbreviation: ED, emergency department;

Table 6.5 Post-education knowledge score between control and intervention subgroups.

Variable	Control			Intervention			p-value
	No.	Mean	Standard deviation	No.	Mean	Standard deviation	
Age							
<36	32	65.31	17.22	39	78.21	13.93	<0.001
≥36	40	58.75	18.97	31	65.48	16.30	0.120
Gender							
Female	29	66.21	12.93	34	71.47	17.43	0.185
Male	43	58.61	20.88	36	73.61	15.15	<0.001
Education							
<High school	13	44.62	18.98	8	66.25	15.06	0.013
≥High school	59	65.42	16.12	62	73.39	16.29	0.008
Injury severity Score							
≦4	55	62.91	18.43	57	74.39	16.48	<0.001
>4	17	57.65	18.21	13	64.62	12.66	0.249
Transferred							
Yes	16	58.75	17.84	19	72.11	14.75	0.021
No	56	62.50	18.61	51	72.75	16.86	0.004
Arrived time							
8-16 h	30	61.00	16.47	36	72.22	18.07	0.011
others	42	62.14	19.82	34	72.94	14.26	0.009
Physician							
Physician A	18	65.00	14.65	16	71.13	20.24	0.186
Physician B	7	58.57	24.78	10	73.00	13.37	0.140
Physician C	14	57.86	18.05	6	70.00	10.95	0.146
Physician D	11	60.00	23.24	12	74.17	13.79	0.087
Physician E	9	67.78	14.81	14	72.14	18.88	0.564
Physician F	13	60.00	19.15	12	71.67	16.42	0.117

Abbreviation: ED, emergency department;

Table 6.6 The difference of knowledge score between control and intervention subgroups.

Variable	Control			Intervention			p-value
	No.	Mean	Standard deviation	No.	Mean	Standard deviation	
Age							
<36	32	9.38	11.34	39	21.80	17.30	<0.001[a]
≥36	40	12.00	11.14	31	14.84	15.46	0.392[a]
Gender							
Female	29	9.31	8.84	34	15.00	15.42	0.084[a]
Male	43	11.86	12.58	36	22.22	17.42	0.003[a]
Education							
<High school	13	9.23	11.15	8	20.00	15.12	0.073[a]
≥High school	59	11.19	11.31	62	18.55	17.07	0.004[a]
Injury severity Score							
≦4	55	11.82	11.56	57	20.35	17.11	0.003[a]
>4	17	7.65	9.70	13	11.54	13.45	0.388[a]
Transferred							
Yes	16	6.25	9.57	19	16.84	14.55	0.015[a]
No	56	12.14	11.40	51	19.41	17.60	0.014[a]
Arrived time							
8-16 h	30	12.00	12.70	36	20.56	18.66	0.031[a]
others	42	10.00	10.12	34	16.76	14.51	0.025[a]
Physician							
Physician A	18	8.33	7.86	16	17.50	17.32	0.066[a]
Physician B	7	11.43	9.00	10	17.00	22.63	0.495[a]
Physician C	14	10.00	10.38	6	16.67	22.51	0.514[a]
Physician D	11	14.55	15.08	12	18.33	17.49	0.583[a]
Physician E	9	15.56	17.40	14	22.14	14.24	0.358[a]
Physician F	13	8.46	8.01	12	19.17	11.65	0.015[a]

[a] Unequal variance test

Abbreviation: ED, emergency department;

Table 6.7 Difference of knowledge score by multiple linear regression model.

	Coefficient	95%CI	p-value
Intervention group	7.646	3.381-11.911	0.001
Age	-0.161	-0.318--0.004	0.044
Gender	1.420	-2.943-5.784	0.521
(reference group=female)			
Education	4.021	-2.577-10.619	0.230
(reference group=<high school)			
Injury severity score	-0.842	-1.513- -0.171	0.014
Transferred	-1.772	-6.724-3.181	0.481
(reference group=non-transferred)			
Arrived time	0.775	-3.730-5.280	0.734
(reference group=other)			
Physician	-1.307	-7.200-4.587	0.662
(reference group=physician 6)			
Baseline knowledge score	-0.379	-0.508--0.249	<0.001
Constant	36.410	22.119-50.701	<0.001
R squared		0.329	

Sample size of regression model = 142.

Abbreviation: ED, emergency department;

Table 6.8 Comparison of satisfaction between control and intervention groups

Outcome	Control No (%)	Intervention No (%)	p-value
I can comprehend the information that healthcare providers provided for the surgery			<0.001
Strongly agree	22 (30.6)	43 (61.4)	
Agree	42 (58.3)	27 (38.6)	
Fair	7 (9.7)	0 (0.0)	
Disagree	0 (0.0)	0 (0.0)	
Strongly disagree	1 (1.4)	0 (0.0)	
The information that healthcare providers provided can help me make a decision for the surgery			<0.001
Strongly agree	29 (40.3)	49 (70.0)	
Agree	38 (52.8)	21 (30.0)	
Fair	4 (5.6)	0 (0.0)	
Disagree	0 (0.0)	0 (0.0)	
Strongly disagree	1 (1.4)	0 (0.0)	
I am satisfied with the informed consent process for the surgery			<0.001
Strongly agree	31 (43.1)	52 (74.3)	
Agree	37 (51.4)	18 (25.7)	
Fair	4 (5.6)	0 (0.0)	
Disagree	0 (0.0)	0 (0.0)	
Strongly disagree	0 (0.0)	0 (0.0)	

Table 6.9 Satisfaction for "I can comprehend the information that healthcare providers provided for the surgery" between control and intervention groups.

Variable	Control		Intervention		p-value
	Strongly agree (n/%)	Others (n/%)	Strongly agree (n/%)	Others (n/%)	
Age					
<36	10(31.3)	22(68.7)	26(66.7)	13(33.3)	0.004
≥36	12(30.0)	28(70.0)	17(54.8)	14(45.2)	0.051
Gender					
Female	11(37.9)	18(62.1)	23(67.7)	11(32.3)	0.024
Male	11(25.6)	32(74.4)	20(55.6)	16(44.4)	0.011
Education					
<High school	4(30.8)	9(69.2)	3(37.5)	5(62.5)	1.000
≥High school	18(30.5)	41(69.5)	40(64.5)	22(35.5)	<0.001
Injury severity score					
≦4	18(67.3)	37(32.7)	36(63.2)	21(36.8)	0.001
>4	4(23.5)	13(76.5)	7(53.9)	6(46.1)	0.132
Transferred					
Yes	4(25.0)	12(75.0)	14(73.7)	5(26.3)	0.007
No	18(32.1)	38(67.9)	29(56.9)	22(43.1)	0.012
Arrived time					
8-16 h	10(33.3)	20(66.7)	22(61.1)	14(38.9)	0.029
others	12(28.6)	30(71.4)	21(61.8)	13(38.2)	0.005
Physician					
Physician A	4(22.2)	14(77.8)	13(81.3)	3(18.8)	0.002
Physician B	2(28.6)	5(71.4)	6(60.0)	4(40.0)	0.335
Physician C	3(21.4)	11(78.6)	3(50.0)	3(50.0)	0.303
Physician D	4(36.4)	7(63.6)	5(41.7)	7(58.3)	1.000
Physician E	4(44.4)	5(55.6)	12(85.7)	2(14.3)	0.066
Physician F	5(38.5)	8(61.5)	4(33.3)	8(66.7)	1.000
Baseline knowledge score					
<60	12(27.9)	31(72.1)	23(60.5)	15(39.5)	0.004
≥60	10(34.5)	19(65.5)	20(62.5)	12(37.5)	0.041
Difference of knowledge score					
≦10	16(32.6)	33(67.4)	17(54.8)	14(45.2)	0.064
>10	6(26.1)	17(73.9)	26(66.7)	13(33.3)	0.003

Abbreviation: ED, emergency department;

Table 6.10 Satisfaction for "The information that healthcare providers provided can help me make a decision for the surgery" between control and intervention groups.

Variable	Control		Intervention		p-value
	Strongly agree (n/%)	Others (n/%)	Strongly agree (n/%)	Others (n/%)	
Age					
<36	17(53.1)	15(46.9)	31(79.5)	8(20.5)	0.023
≥36	12(30.0)	28(70.0)	18(58.1)	13(41.9)	0.029
Gender					
Female	13(44.8)	16(55.2)	24(70.6)	10(29.4)	0.045
Male	16(37.2)	27(62.8)	25(69.4)	11(30.6)	0.006
Education					
<High school	4(30.8)	9(69.2)	4(50.0)	4(50.0)	0.646
≥High school	25(42.4)	34(57.6)	45(72.6)	17(27.4)	0.001
Injury severity score					
≦4	22(40.0)	33(60.0)	41(71.9)	16(28.1)	0.001
>4	7(41.2)	10(58.8)	8(61.5)	5(38.5)	0.462
Transferred					
Yes	6(37.5)	10(62.5)	13(68.4)	6(31.6)	0.095
No	23(41.1)	33(58.9)	36(70.6)	15(29.4)	0.003
Arrived time					
8-16 h	11(36.7)	19(63.3)	25(69.4)	11(30.6)	0.013
others	18(42.9)	24(57.1)	24(70.6)	10(29.4)	0.021
Physician					
Physician A	7(38.9)	11(61.1)	12(75.0)	4(25.0)	0.045
Physician B	3(42.9)	4(57.1)	7(70.0)	3(30.0)	0.350
Physician C	4(28.6)	10(71.4)	3(50.0)	3(50.0)	0.613
Physician D	4(36.4)	7(63.6)	9(75.0)	3(25.0)	0.100
Physician E	5(55.6)	4(44.4)	12(85.7)	2(14.3)	0.162
Physician F	6(46.2)	7(53.8)	6(50.0)	6(50.0)	1.000
Baseline knowledge score					
<60	16(37.2)	27(62.8)	25(65.8)	13(34.2)	0.014
≥60	13(44.8)	16(55.2)	24(75.0)	8(25.0)	0.020
Difference of knowledge score					
≦10	22(44.9)	27(55.1)	20(64.5)	11(35.5)	0.110
>10	7(30.4)	16(69.6)	29(74.4)	10(25.6)	0.001

Abbreviation: ED, emergency department;

Table 6.11 Satisfaction for "I am satisfied with the informed consent process for the surgery" between control and intervention groups.

Variable	Control		Intervention		p-value
	Strongly agree (n/%)	Others (n/%)	Strongly agree (n/%)	Others (n/%)	
Age					
<36	16(50.0)	16(50.0)	34(87.2)	5(12.8)	0.001
≥36	15(37.5)	25(62.5)	18(58.1)	13(41.9)	0.099
Gender					
Female	15(51.7)	14(48.3)	26(76.5)	8(23.5)	0.063
Male	16(37.2)	27(62.8)	26(72.2)	10(27.8)	0.003
Education					
<High school	5(38.5)	8(61.5)	4(50.0)	4(50.0)	0.673
≥High school	26(44.1)	33(55.9)	48(77.4)	14(22.6)	<0.001
Injury severity score					
≦4	22(40.0)	33(60.0)	44(77.2)	13(22.8)	<0.001
>4	9(52.9)	9(47.1)	8(61.5)	5(38.5)	0.721
Transferred					
Yes	5(31.3)	11(68.7)	14(73.7)	5(26.3)	0.018
No	26(46.4)	30(53.6)	38(74.5)	13(25.5)	0.003
Arrived time					
8-16 h	11(36.7)	19(63.3)	27(75.0)	9(25.0)	0.003
others	20(47.6)	22(52.4)	25(73.5)	9(26.5)	0.034
Physician					
Physician A	7(38.9)	11(61.1)	13(81.3)	3(18.8)	0.017
Physician B	5(71.4)	2(28.6)	7(70.0)	3(30.0)	1.000
Physician C	4(28.6)	10(71.4)	4(66.7)	2(33.3)	0.161
Physician D	4(36.4)	7(63.6)	9(75.0)	3(25.0)	0.100
Physician E	5(55.6)	4(44.4)	12(85.7)	2(14.3)	0.162
Physician F	6(46.2)	7(53.8)	7(58.3)	5(41.7)	0.695
Baseline knowledge score					
<60	17(39.5)	26(60.5)	27(71.1)	11(28.9)	0.007
≥60	14(48.3)	15(51.7)	25(78.1)	7(21.9)	0.019
Difference of knowledge score					
≦10	23(46.9)	26(53.1)	20(64.5)	11(35.5)	0.168
>10	8(34.8)	15(65.2)	32(82.1)	7(17.9)	<0.001

Abbreviation: ED, emergency department;

Table 6.12 Multivariable logistic regression model for satisfaction

	I can comprehend the information that healthcare providers provided for the surgery		The information that healthcare providers provided can help me make a decision for the surgery		I am satisfied with the informed consent process for the surgery	
	Odds ratio	95% CI	Odds ratio	95% CI	Odds ratio	95% CI
Intervention group (reference group= control group)	3.299**	1.614-6.746	3.246**	1.567-6.727	3.702**	1.747-7.843
Age (reference group= age<36)	0.703	0.326-1.515	0.379*	0.175-0.822	0.371*	0.168-0.821
Gender (reference group=female)	0.552	0.260–1.175	0.770	0.359-1.653	0.578	0.264-1.264
Education (reference group=<high school)	1.243	0.412–3.752	1.230	0.414-3.654	1.119	0.379-3.303
Injury severity score (ISS) (reference group= ISS≦4)	0.654	0.268-1.595	0.849	0.353-2.039	1.031	0.421-2.523
Transferred (reference group=non-transferred)	1.307	0.578-2.955	0.883	0.383-2.036	0.669	0.287-1.563
Arrived time (reference group=other)	1.222	0.582-2.568	0.972	0.459-2.058	0.923	0.430-1.981
Physician (reference group=physician A)	0.733	0.313-1.715	0.904	0.381-2.145	0.938	0.387-2.273
Baseline knowledge score (BKS) (reference group= BKS<60)	0.965	0.453-2.057	1.195	0.557-2.567	1.134	0.520-2.473
Likelihood ratio test for model	$\chi 2$= 19.41; P =0.022		$\chi 2$= 22.13; P =0.009		$\chi 2$=24.83; P =0.003	

*p< 0.05; **p<0.01. Sample size of regression model = 142.

Abbreviation: ED, emergency department;

CHAPTER SEVEN

Summary and Discussion

Summary of main findings

Informed consent is an important issue for trauma patients in the emergency department. Healthcare providers and institutions should develop strategies to improve the informed consent process in the best interest of patients. There is a vast amount of articles published in the field of informed consent, but only a few have focused on the population of trauma patients. The investigators found that trauma patients had poor recall of risks and complications, while written information, pamphlet, or video had positive effect on patients' understanding and satisfaction. No empirical evidence has supported the success of informed consent for trauma patients in the emergency department, especially within the very limited time frame.

The Delphi technique is a good method to collect experts' opinions and reach consensus for the contents of informed consent and educational video. The educational video is a useful tool to improve the knowledge and satisfaction of trauma patients in the emergency department. Institutions should give top priority to patient-centered health care, and develop a structured informed consent process to improve quality of care.

Using educational videos is a good tool for improving informed consent process for the surgery of debridement in trauma patients. Video-assisted informed consent may improve patient understanding of the surgery of debridement and satisfaction with the process of informed consent in trauma patients.

Future studies should be conducted to develop a structured and standardized informed consent process and evaluate the effectiveness in combination with healthcare providers, patients, and informed consent experts. Institutions should give top priority to ensure patient-centered health care and improved quality of care for trauma patients.

Limitations and Strengths

The study has several limitations. In the systematic review, the searched articles are quite rare, and meta-analysis and quantitative analysis are not possible because of the heterogeneity of data. Because the articles are rare and the study samples are relatively small, publication bias might be possible. The results reveal a positive effect, but there might be possible negative effect for unpublished articles.

In the pilot study, because it was not a randomized controlled study design, there might be many confounders limiting our inferences. In the Delphi rounds, though the experts in this study comprised a variety of specialties, it was possible that their opinions might not have reflected the whole picture for the matter studied. Further studies might be needed to include more experts with a broader spectrum of specialties to provide more thorough opinions. Furthermore, the injury severities of trauma patients vary and might have an influence on their consent process and perceptions of satisfaction. Future studies are needed to explore these associations.

The study is based on one pilot study and at an exploratory stage aiming for a viable alternate to current practice. The pilot study and randomized controlled trial represent specific surgeries conducted at one institution only, and the results may not be generalized to other surgeries or institutions. The study did not evaluate the effect of the educational video on patient's anxiety. Further researches are needed to confirm this effectiveness. In our study, the information retention has not been evaluated. Further researches are recommended to explore the effectiveness of an educational video on the information retention and patient satisfaction for trauma patients. Moreover, due to the uncertainty of trauma surgery, some eligible cases might be missed, and the time to collect data from eligible cases is time-consuming.

This study has several strengths. The search strategy is comprehensive. As far as we know, no other review study focuses on this topic. In the randomized controlled trial, randomization may balance patient background and knowledge of the surgery

between each group. Baseline knowledge measure was formally tested and may limit some potential bias (such as healthcare factors or patients' previous exposure to the surgery, etc.) that may have an influence on post-education measures to reflect the actual improvement of the intervention. Moreover, the study has several important elements that have never been studied before, including the video containing the informed consent information for trauma surgery, the knowledge measurement for trauma surgery, and study population in the emergency setting.

Implication of the study

Implication for future researches

Informed consent in trauma patients is very important but rarely studied in this field. Further studies for informed consent process in trauma patients in detail have been recommended. More research is needed to explore the factors predicting patient's understanding and satisfaction during informed consent process for trauma patients. Moreover, more research is needed to support the effectiveness of different information delivery methods on informed consent in trauma patients, and develop a standardized tool for evaluating patient's understanding. The most effective strategy for the process is necessary to be developed and established.

Furthermore, how to provide adequate education and train healthcare providers to deliver structured and comprehensive information to trauma patients in a very timely manner as well as, at the same time, establish a good patient-physician relationship and build trust are also important issues worth further exploring.

Moreover, informed consent might be waived when the patients are in medical emergency. Further research is needed in exploring how many trauma patients undergo emergency surgeries without informed consent or surrogate consent, and how the healthcare providers define such medical emergencies. More research is needed for the relationship between patients' outcome and their decision-making.

Implication for policy and practice

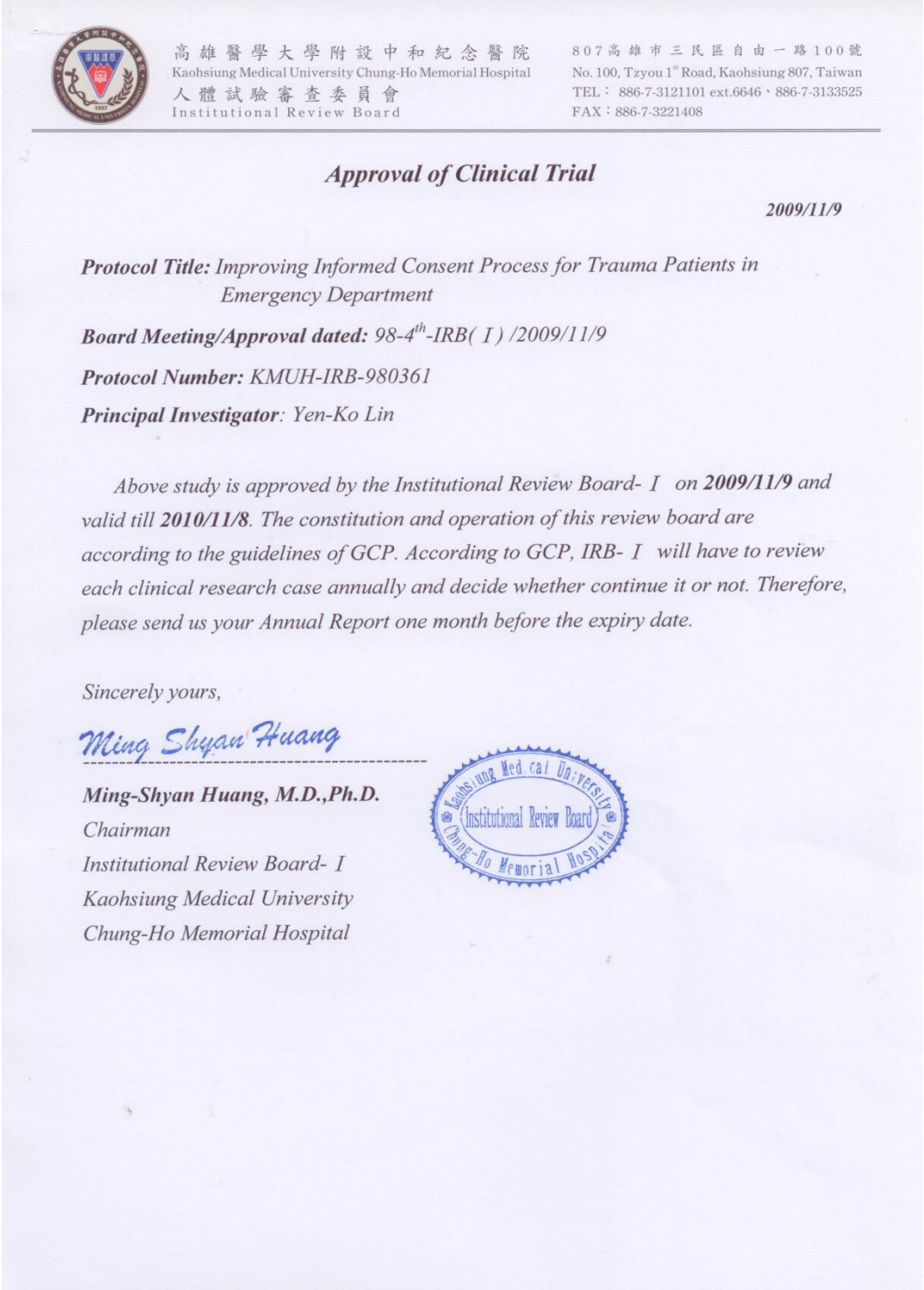
Computerized and interactive programs might provide patients with tailor-made and individualized information to help patients comprehend all the necessary information in a very short time frame. We believe that information aids might have many advantages for trauma patients.

For trauma patients, the audiovisual video may help them understand the complete information about the surgery, facilitate medical decision-making, and

improve satisfaction. The institution should develop the strategies and structured methods to better inform trauma patients to facilitate decision-making about their treatment, and improve patient satisfaction. For healthcare providers, the audiovisual video may be a good tool to improve the communication between healthcare providers and patients, and facilitate the treatment decision.

APPROVAL OF CLINICAL TRIAL

The study protocol has been reviewed by the Institutional Review Board of the Kaohsiung Medical University Hospital before the study begins. Patients in the control and intervention groups for this study have signed written informed consents before enrollment. The ClinicalTrials.gov Identifier is NCT01338480.



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Approval of Clinical Trial

2009/11/9

Protocol Title: *Improving Informed Consent Process for Trauma Patients in Emergency Department*

Board Meeting/Approval dated: *98-4th-IRB(I) /2009/11/9*

Protocol Number: *KMUH-IRB-980361*

Principal Investigator*: Yen-Ko Lin*

*Above study is approved by the Institutional Review Board- I on **2009/11/9** and valid till **2010/11/8**. The constitution and operation of this review board are according to the guidelines of GCP. According to GCP, IRB- I will have to review each clinical research case annually and decide whether continue it or not. Therefore, please send us your Annual Report one month before the expiry date.*

Sincerely yours,

Ming Shyan Huang

Ming-Shyan Huang, M.D.,Ph.D.
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修正計畫同意書

計畫名稱：急診部門外傷病患之知情同意流程改善計畫

人委會編號：KMUH-IRB-980361

計畫主持人：林彥克

修正內容/版本：

1.計畫書（版本日期：第二版）

本計畫修正案經 **2011** 年第一人體試驗審查委員會第 5 次審查會議（二〇一一年五月十九日）審查通過，特此 證明。

高雄醫學大學附設中和紀念醫院
第一人體試驗審查委員會
主任委員 侯明鋒

二　O　一　年　五　月　十　九　日

Certificate of Approval

2011/5/19

The following documents have been submitted for review.
Protocol Title: *Improving Informed Consent Process for Trauma Patients in Emergency Department*
IRB No.: *KMUH-IRB-980361*
Principal Investigator: *Yen-Ko Lin*
Board Meeting/Approval dated: *2011-5th-IRB(I)/2011/5/19*
Reason for Amendment/Version:
1. Protocol *(Version Date: Version 2)*

Sincerely yours,

Ming-Feng Hou

Ming-Feng Hou, M.D.,Ph.D.
Chairman
Institutional Review Board- I
Kaohsiung Medical University
Chung-Ho Memorial Hospital

CURRICULUM VITAE

YEN-KO LIN

POSITION

Attending Physician, Division of Traumatology, Department of Surgery, Kaohsiung Medical University Hospital
Assistant Professor, Department of Medical Humanities and Education, Kaohsiung Medical University
Deputy Secretary General, Formosa Association for the Surgery of Trauma

CONTACT INFORMATION

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EDUCATION

Dr.P.H.	2006-present	Department of Health Policy and Management Johns Hopkins University
M.BE.	2005-2007	Department of Medical Ethics University of Pennsylvania
M.S.	1995-1997	Graduate Institute of Heath Care Organization Administration National Taiwan University
M.D.	1988-1995	Kaohsiung Medical College

HONORS & AWARDS

2003	Young Scholar Research Award, Kaohsiung Medical University
2007	Teaching award, Kaohsiung Medical University Hospital
2008	Outstanding Research Paper Award, Formosa Association for the Surgery of Trauma
2013	Teaching award, Kaohsiung Medical University Hospital
2014	Outstanding Research Paper Award, Kaohsiung Medical University

PROFESSIONAL EXPERIENCE

2014-	Committee member, Trauma Nurse Training Program, Taiwan Association of Critical Care Nurse
2013-	Executive secretary, Health Law Education, Kaohsiung Medical

	University Hospital
2010-	Committee member, Medical Education Committee, Kaohsiung Medical University Hospital
2009-	Committee member, Faculty Development Committee, Kaohsiung Medical University Hospital
2009-	Reviewer, Institutional Review Board, Kaohsiung Medical University Hospital
2007-	Advanced Trauma Life Support instructor, American College of Surgeons
2007-	Executive secretary, Medical Ethics Committee, Kaohsiung Medical University Hospital
2004-2005	Deputy executive, Kaohsiung Emergency Medical Operation Center

PROFESSIONAL MEMBERSHIP

2010-	Member, Taiwan Society of Critical Care Medicine
2008-	Member, Formosa Association for the Surgery of Trauma
2007-	Member, Taiwan Society of Emergency Medicine
2002-	Member, Taiwan Orthopaedic Association
2001-	Member, Taiwan Surgical Association

RESEARCH GRANTS AWARDED

2014/08/01~2017/07/31	Establishing feedback information system from patient and family satisfaction with acute care transfers, Taiwan National Science Council
2014/08/01~2016/07/31	Medical Students' perception and preparedness of cross-cultural care competence: medical students' and teachers' perspectives, Taiwan National Science Council
2015/08/01~2017/07/31	Association of national cultural dimensions with clinical learning environment measurement and clinical teacher's teaching performance, Taiwan National Science Council

PAPERS

1. Soo KM, Lin TY, Chen CW, **Lin YK**, Kuo LC, Wang JY, Lee WC, Lin HL. More becomes less: management strategy has definitely changed over the past decade of splenic injury--a nationwide population-based study. Biomed Res Int.

2015;2015:124969. doi: 10.1155/2015/124969. Epub 2015 Jan 5.

2. Hsiao CY, Lin HL, **Lin YK**, Chen CW, Cheng YC, Lee WC, Wu TC. Urinary tract infection in patients with chronic kidney disease. Turk J Med Sci. 2014;44(1):145-9.
3. Lin HL, **Lin TY**, Soo KM, Chen CW, Kuo LC, Lin YK, Lee WC, Lin CL. The effect of alcohol intoxication on mortality of blunt head injury. Biomed Res Int. 2014;2014:619231. doi: 10.1155/2014/619231. Epub 2014 Aug 4.
4. Lin HL, Soo KM, Chen CW, **Lin YK**, Lin TY, Kuo LC, Lee WC, Huang SL. Incidence, national trend, and outcome of nontraumatic subarachnoid haemorrhage in Taiwan: initial lower mortality, poor long-term outcome. Biomed Res Int. 2014;2014:274572. doi: 10.1155/2014/274572. Epub 2014 Mar 31.
5. Lee WC, Chen CW, **Lin YK**, Lin TY, Kuo LC, Cheng YC, Soo KM, Lin HL. Association of head, thoracic and abdominal trauma with delayed diagnosis of co-existing injuries in critical trauma patients. Injury. 2014 Sep;45(9):1429-34. doi: 10.1016/j.injury.2014.01.017. Epub 2014 Jan 28.
6. **Lin YK**, Lee WC, Kuo LC, Cheng YC, Lin CJ, Lin HL, Chen CW, Lin TY. Building an ethical environment improves patient privacy and satisfaction in the crowded emergency department: a quasi-experimental study. BMC Med Ethics. 2013 Feb 20;14:8. doi: 10.1186/1472-6939-14-8.
7. **Lin YK**, Lin CJ, Chan HM, Lee WC, Chen CW, Lin HL, Kuo LC, Cheng YC. Surgeon commitment to trauma care decreases missed injuries. Injury. 2014 Jan;45(1):83-7. doi: 10.1016/j.injury.2012.10.019. Epub 2012 Nov 3.
8. Tang CL, Lee SS, Lin TY, **Lin YK**, Yeh YS, Lin HL, Lee WC, Chen CW. Empty toe: a unique type of closed degloving injury with dismal outcome. Am J Emerg Med. 2013 Jan;31(1):263.e1-3. doi:
9. Lou YT, Lin HL, Lee SS, Lee WC, Kuo LC, Cheng YC, Lin TY, **Lin YK**, Chen CW. Conductor-assisted nasal sonography: an innovative technique for rapid and accurate detection of nasal bone fracture. J Trauma Acute Care Surg. 2012 Jan;72(1):306-11. doi: 10.1097/TA.0b013e318227a239.
10. Lin HL, Lee WC, Chen CW, Lin TY, Cheng YC, Yeh YS, **Lin YK**, Kuo LC. Neck collar used in treatment of victims of urban motorcycle accidents: over- or underprotection? Am J Emerg Med. 2011 Nov;29(9):1028-33. doi: 10.1016/j.ajem.2010.06.003. Epub 2010 Oct 15.
11. Lee WC, Kuo LC, Cheng YC, Chen CW, **Lin YK**, Lin TY, Lin HL. Combination of white blood cell count with liver enzymes in the diagnosis of blunt liver laceration. Am J Emerg Med. 2010 Nov;28(9):1024-9. doi: 10.1016/j.ajem.2009.06.005. Epub 2010 Mar 25.

12. Lin HL, Lee KT, Chen CW, Kuo LC, **Lin YK**, Cheng YC, Lee WC. Management of motorcycle accident-related blunt hepatic injury-a different strategy. Am J Emerg Med. 2010 Feb;28(2):177-82. doi: 10.1016/j.ajem.2008.11.001.