

**PROCEDURAL SEDATION ANALGESIA IN
EMERGENCY DEPARTMENT: SURVEY ON
KNOWLEDGE AND PRACTICE AMONG NON-
ANAESTHETIC DOCTORS IN HOSPITAL
UNIVERSITI SAINS MALAYSIA (HUSM)**

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LIST OF ABBREVIATION

ACEP	American College of Emergency Physician
ENT	Ear, Nose and Throat
CT	Computed Tomography
HUSM	Hospital Universiti Malaysia
PSA	Procedural Sedation and Analgesia

ABSTRAK

Tajuk : Prosedural Sedatif dan Analgesia di Jabatan Kecemasan: Kajian tentang pengetahuan dan amalan di kalangan doktor bukan anestetik di Hospital Universti Malaysia (HUSM).

Latarbelakang : Prosedural Sedatif dan Analgesia merujuk kepada teknik memberikan agen sedatif dengan atau tanpa analgesia untuk menjadikan pesakit lebih toleran pada prosedur yang tidak menyenangkan dalam keadaan hemodinamik yang stabil.

Objektif: Kajian ini bertujuan untuk mengenalpasti tahap pengetahuan dan amalan berkaitan procedural sedative dan analgesia di kalangan dokto bukan anestetik dari subgrup medikal dan surgical. Dalam analisis untuk membezakan tahap pengetahuan dan amalan kedua-dua kumpulan ini, factor demografik yang mempengaruhi tahap pengetahuan dalam PSA juga dapat dikenalpasti.

Kaedah : Kajian ini dijalankan secara prospektif dan “cross-sectional” merangkumi 144 doktor bukan anestetik yang terlibat dalam procedural sedative dan analgesia di jabatan kecemasan HUSM. Borang soal selidik diagihkan dalam jumlah yang sama kepada dua subgrup medikal dan surgical. Kajian dijalankan dari bulan Januari 2013 sehingga bulan Disember 2014.

Keputusan : Keseluruhan 144 responden berumur dalam lingkungan 24 hingga 37 tahun dengan min umur 30 tahun. Min markah tahap pengetahuan tentang PSA untuk kumpulan medikal sebanyak 8.06 berbanding 6.60 markah untuk kumpulan surgical. Tiada perbezaan signifikan antara tahap pengetahuan kumpulan medical (nilai p 0.299) dan surgical (nilai p 0.233). Doktor dari kumpulan medikal menunjukkan amalan baik yang lebih ketara dalam mengendalikan PSA di mana mereka prihatin dengan protocol yang sedia ada, melengkapkan pemerhatian tanda vital sepanjang prosedur,

dan menerima pendidikan formal sebelum mengendalikan PSA. Umur, tahap pendidikan, dan tempoh dalam perkhidmatan memberikan korelasi positif terhadap tahap pengetahuan (0.5-0.64)

Kesimpulan: Tiada perbezaan ketara tahap pengetahuan berkaitan prosedural sedatif dan analgesia antara kumpulan doktor bukan anestetik medikal dan surgikal HUSM. Doktor dari kumpulan medikal mengamalkan amalan yang lebih baik dalam procedural sedatif dan analgesia. Peningkatan umur, tahap pendidikan, dan tempoh dalam perkhidmatan menentukan tahap pengetahuan yang lebih tinggi tentang PSA.

ABSTRACT

Procedural Sedation Analgesia in Emergency Department: Survey on knowledge and practice among non-anaesthetic doctors in Hospital Universiti Malaysia (HUSM)

Background: Procedural Sedation and Analgesia refers to a technique of administering sedatives with or without analgesia to induce a state allowing patients to tolerate unpleasant procedures while being hemodynamically stable.

Objectives: This study intended to identify the level of knowledge and practice of procedural sedation and analgesia among two subgroups of non- anaesthetic doctors; medical and surgical based. By comparing the mean of knowledge and practice level between these two major subgroups, demographic factors that influence the knowledge level will also be determined.

Methodology: This is a prospective cross sectional study involving 144 non anaesthetic doctors involved in procedural sedation and analgesia in the emergency department HUSM. A questionnaire survey were conducted among equally distributed respondents from two subgroups which is medical and surgical based. This study was conducted from January 2013 to December 2014.

Results: The total of 144 respondents aged from 24 to 37 years old with mean age of 30 years old. Mean score of knowledge level in PSA for medical-based doctors is 8.06 compared to 6.60 marks of those in surgical based. There was no significant difference between knowledge level of PSA among medical-based (p value 0.299) and surgical-based (p value 0.233) non anaesthetic doctors in HUSM. Medical based doctors displayed significantly better practices by being aware of protocol available, completing vital signs monitoring, and

having formal teaching prior to handling drugs for PSA (p value <0.01). Age, level of education and service years gave positive correlation towards level of knowledge (0.5-0.64).

Conclusion: There was no significant difference of knowledge level between medical based and surgical based non anaesthetic doctors in HUSM though both groups revealed more than average knowledge level. Medical based doctors displayed significant good practices in performing procedural sedation analgesia. Older age, higher level of education, and longer service years contributed to higher knowledge level in procedural sedation and analgesia.

CHAPTER 1: INTRODUCTION

Overview of PSA

Procedural Sedation and Analgesia (PSA) refers to a technique of administering sedatives with or without analgesics to induce a state allowing patients to tolerate unpleasant procedures while maintaining cardiorespiratory function (ACEP, 2005). This technique has to be effective in reducing stress response experienced by patients and improving their compliances with procedures planned (Rahman et al, 2010). Emergency services particularly the emergency department has confidently adopted this skills in conducting short-timed procedures so as to fasten patient's disposition and reducing admission rates.

Emergency department is a unique environment where variety of patients are managed for their emergent and urgent conditions (ACEP Clinical Policy 2004). In majority of situations, sedation is administered by non-anaesthetic doctors in locations outside the operating theatre, and emergency department is one of it (Fanning, 2007). Emergency physicians have a well-established track record of safe sedation (O'Connor et al, 2011).

Non-anaesthetic doctors refer to certified medical doctors not formally trained in anaesthesia, specifically including emergency doctors and non-emergency doctors from paediatrics, medical, general surgery, orthopaedics, plastic and reconstructive unit, otorhinolaryngology, ophthalmology and dentistry. Inclusion of physicians other than the emergency doctors in this study is of equal importance as they are the ones performing the

actual procedure after initiation of effective sedation by the emergency physician, hence part of the team responsible in providing best available service for patients' sake. These groups of non-anaesthesiologist doctors are of emphasis in this study as they are not formally trained in administering procedural sedation, but are given the privilege to conduct and be directly involved with such procedure in the emergency department.

Sufficient knowledge and good anticipation of complications that might arise with usage of such drugs commonly used by the anaesthetic doctors are greatly needed by these groups of doctors, with emergency doctors of higher concern. The need in evaluating the knowledge obtained, and practice carried throughout the procedure, is of greater importance so as to safeguard patients' safety.

Typical procedures performed under PSA in the emergency department are closed manual reduction of fractures and common dislocations, incision and drainage of abscesses, laceration repair in children, foreign body removal, cardiac pacing or synchronised cardioversion, chest tube insertion for drainage, sedation for radiological procedures such as CT scan, and dressing of large areas for patients unable to tolerate pain (Campbell et al, 2008). Procedural sedation offers excellent muscle relaxation and pain relief to facilitate reduction of dislocation (Hendey, 2015). Electrical cardioversion for instance, is painful and requires sedation and analgesia usually with the intravenous agents (G. Ozkan et al, 2016).

Drugs that are commonly used for procedural sedation with or without analgesia are Propofol, Ketamine, Fentanyl, and Midazolam either as a single drug or in combination. Propofol has been shown to be safe and effective, with minimal adverse events when used in PSA (Mensour et al, 2006). Ketamine is useful due to its excellent analgesic property with lower incidence of respiratory depression. Hence, it plays an important role in procedural sedation in the Emergency Department, including paediatric emergencies (Mei GAO et al, 2016). Ketamine used most in paediatric sedation and Propofol used frequently for dislocation reduction in adults (Holdgate et al, 2011). Various short acting drugs such as Midazolam, Diazepam, Thiopental, Etomidate, Propofol and opioids like Fentanyl or combinations have been used for procedures such as electrical cardioversion (G.Ozkan et al, 2016). These usage greatly depends on the knowledge and familiarity with the drugs by the doctors involved (Gorchynski et al, 2006). Sufficient number of studies were done and it is proven that all these drugs can be safely administered in the emergency department provided proper monitoring availability.

Such guidelines for sedation and analgesia by non-anaesthesiologists exist and designed by the American Society of Anaesthesiologist Task Force in 1995, and revised in 2002. Locally, College of Anaesthesiologists Academy Medicine of Malaysia has published a recommended guideline in 2012 for the said practice. It is applicable to procedures performed in settings other than the operating room by practitioners who are not specialists in anaesthesiology. The aim of such guideline is to allow clinicians in providing patients with the benefits of sedation and analgesia while minimising associated risk.

Several local and numerous international studies have been conducted in assessing safety of drugs commonly used in procedural sedation and analgesia in the emergency department. Based on our limited literature review regarding assessment of the current practice in view of the operators' knowledge and practicality, none of this were done in the local population. This study is important as a platform to determine the need for formal and continuous training and assessment regarding procedural sedation and analgesia for the non-anaesthesiologists.

CHAPTER 2: LITERATURE REVIEW

A study done by Ruth M. Fanning in 2007 assessed the practice of sedation administered by non-anaesthetist doctors in a number of university teaching hospitals in Dublin, Ireland. A questionnaire survey was carried out among trainees at all levels of specialist training from multiple disciplines involved in procedural sedation and analgesia in various locations such as emergency department, endoscopy and bronchoscopy suites, cardiac labs, general wards, radiology department and minor surgical theatres. Questionnaires revealed that small proportion of respondents (42/111; 38%) had received formal training in the administration of sedation, and 55% (61/111) were aware that principles and practices of sedation and sedative medications were included in their core curriculum. It was disturbingly found that respondent's knowledge of the pharmacology of drugs used was poor, with majority (107/111; 96%) using set boluses rather than weight-based calculated dose hence increasing the risk of unwanted adverse effects. (R.M.Fanning, 2007)

Subsequent study using the same questionnaire by Fanning was conducted among 53 specialist registrars in orthopaedic and trauma at a regional teaching sessions in Swansea and Bristol. Their clinical practice, knowledge, and training with regards to sedation practiced in the emergency department were assessed. Satisfactorily, almost all (98%) respondents administered sedation in the presence of assistant. Drugs commonly used were opioids.

However, 80% of surveyed orthopaedic doctors (43 respondents) reported adverse events occurred after administering sedation, including hypoxia, respiratory depression,

hypotension, nausea and vomiting, and unconsciousness. A retrospective descriptive study was done in the Emergency Department of False Bay Hospital, Cape Town in assessing the safety and efficacy of procedural sedation and analgesia (PSA) conducted by medical officers. This 29 months duration study concluded that procedural sedation and analgesia can be safely administered by medical officers, and all of them involved in this study had attended ACLS (advanced cardiac life support), ATLS (advanced trauma life support), and PALS (paediatric advanced life support) courses (Wenzel-Smith et al, 2011)

In a study done at an emergency department of a large tertiary level hospital in New Zealand, all sedations were performed by Emergency Medicine faculty. Forty nine (84%) of actual procedures were performed by Emergency Medicine doctors, 97(16%) by doctors from other specialty. (65 orthopaedics, 13 plastic surgery, 19 others) (Harvey et al, 2011).

The literature supporting the safety and efficacy of ED procedural sedation and analgesia is robust, and includes large series in both adults and children using moderate, dissociative, and deep sedation (Mallory M. et al, 2011). There is no evidence to suggest that emergency-physician directed sedation is less safe or of lower quality than that delivered by any other specialist, and safety equivalence to that administered by anaesthesiologist are supported by large clinical studies (O'Connor et al, 2011). In O'Connor's review on ACEP sedation position within the same citation, it is recommended that each emergency medicine service should participate in a departmental and/or institution-wide multidisciplinary quality assurance program which monitors procedural sedation and analgesia practice, tracks

adverse events, ensures satisfactory documentation and compliance with protocols, and identifies opportunities for improvement

2.1 Sedation and Analgesia by Non-Anaesthesiologists Guidelines and Recommendations

2.1.1 International Recommendations

American College of Emergency Physicians (ACEP) makes the following recommendations for sedation practice under the endorsement of an emergency medicine service.

- 1) Pre sedation evaluation: Type of sedation used is to be appropriate based on the pain and distress typical for the procedure and patient's anxiety, cooperativeness, age, and health. Emergency physician will discuss the plan to administer sedation with the patient and other team members, and appropriate consent will be obtained either verbal or written. Lack of fasting is not a contraindication for administering procedural sedation, but the timing and target level of sedation in these non-fasted patients should be seriously considered (Green SM et al, 2007).

- 2) Procedural sedative agents: The selection of specific sedatives or analgesic agents should be tailored to each patient by the emergency physician and should not be restricted.

- 3) Adjunctive techniques: Other than pharmacologic means, non-pharmacologic aids such as distraction, visual imagery or even temporary physical immobilisation might be useful in reducing pain-and fear-related movements due to the procedure planned.

- 4) Interactive monitoring: Deep sedation may be accomplished with the emergency physician administering sedation and monitoring the patient, whilst a separate practitioner perform the procedure. Given that emergency department procedures are usually brief and can be readily interrupted, certain circumstances permitted for deep sedation to be performed singly by an emergency physician and a nurse to conduct monitoring.

- 5) Mechanical monitoring: Vital signs should be measured at appropriate intervals, at minimum before, during, and after sedation. Emergency physicians will assess the patient on an ongoing basis during such procedure to ensure that appropriate levels of sedation, analgesia, and anxiolysis have been achieved. Continuous pulse oximetry should be of routine during moderate to deep sedation levels. Continuous capnography is not mandatory, but is increasingly being recommended in providing earliest possible warning of hypoxia and hypoventilation (Deitch K. Et al, 2010).

- 6) Other equipment and supplies: Sedation should be performed in an area with oxygen, suction, medications, and equipment for advanced airway management if required. Reversal agents should be available when opioids or benzodiazepines are in use.

- 7) Intravenous access: Need for intravenous access is dependent on the medications, dosage, and route used. Ketamine is proven to be efficacious and safe to be used intramuscularly (Green SM et al, 2011).

- 8) Supplemental oxygen: Emergency department sedation is widely practiced with or without supplemental oxygen, and such use is left to the physician's discretion (Deitch K. Et al, 2008).

- 9) Recovery: Patients who had undergone sedation should be monitored until they are no longer at risk for respiratory depression, stable vital signs, alert, and at age-appropriate baseline level of consciousness (Krauss B. Et al, 2006). Documentation should reflect how well the patient tolerated procedure done, patient's condition post procedure, and when transfer and discharge took place.

Our neighbouring country Singapore has come up with their own guideline on safe sedation practice for non-anaesthetic doctors in medical clinics, including stand-alone ambulatory surgical centres and stand-alone endoscopy suites in May 2014. Main contributors in their guideline are anaesthesiologists, physicians, and surgeons. However this guideline stated that it is not applicable for procedural sedation in emergency departments or other ambulatory surgical clinics in hospital setting.

2.1.2 National Guideline for Sedation and Analgesia by Non Anaesthesiologists

College of Anaesthesiologists Academy of Medicine Malaysia has come up with a guideline on sedation and analgesia by non-anaesthesiologists in December 2012. Unlike Singapore, our national guideline committee members included contributions from most departments involved with procedural sedation outside operating room with emergency physicians on board. Hence, it is applicable for all non-operating room locations including emergency department. As a general rule, a registered medical practitioner (RMP) or registered dental practitioner (RDP) must be trained to carry out procedural sedation. Such guideline is more pertinent to our practice in Malaysia.

Administration of Procedural Sedation

Pre-procedure

- 1) Assessment of patient should be done pre-procedure including relevant medical, surgical and allergy history. Any past sedation and analgesia undergone and their experiences throughout should be obtained in anticipating potential airway or adverse effects of sedation given.
- 2) Patients who may require an anaesthesiologist to administer sedation are to be identified as they are of increased risk of airway, respiratory or cardiovascular compromise. Decision to call upon the assistance will be made by the RMP/RDP. These include patients who:
 - a) are elderly, especially with co-morbidities
 - b) have significant cardiovascular, lung, renal or liver disease
 - c) are morbidly obese
 - d) have significant obstructive sleep apnoea
 - e) are a known or suspected difficult endotracheal intubation case
 - f) have acute gastrointestinal bleeding with shock
 - g) are at great risk of aspiration
 - h) have had previous adverse events due to sedation, analgesia or anaesthesia
 - i) have history of substance abuse
- 3) Patient should be adequately explained regarding the procedural sedation including risks, with written consent as appropriate
- 4) Procedure should preferably be done in office hours when help is more readily available should need arise.

Administration of Sedation

- 1) The RMP/RDP administering the drugs for sedation and analgesia should:
 - a) establish an intravenous access prior to procedure
 - b) have sound knowledge of the actions of drugs to be administered, and be able to adjust the dosage, particularly in patients with co-morbidities and history of chronic substance abuse
 - c) monitor the patient's level of consciousness and cardiorespiratory status
 - d) be able to detect and manage possible complications including cardiorespiratory resuscitation.
- 2) The prescription of the sedatives is the responsibility of the RMP/RDP.
- 3) Intravenous anaesthetics such as Propofol are to be used only by trained RMP/RDP in view of its risk to cause unintentional loss of consciousness.
- 4) Sedative drugs should be carefully titrated rather than fixed dosage. Use of antagonists to opioids and benzodiazepines should only be used in emergency situation, not as routine administration at the end of procedure.

Patient Support And Monitoring

- 1) Continuous monitoring of vitals such as blood pressure, pulse rate, oxygen saturation, and depth of sedation should be done throughout the procedure.
- 2) Appropriate trained assistant to the RMP/RDP must be present to monitor the cardiorespiratory status of patient and immediately respond should the need arise.

- 3) Patient's oxygen saturation should be closely monitored with preset alarm should the saturation falls.
- 4) Supplemental oxygen should be administered during the procedure, particularly those undergoing airway or endoscopies.
- 5) Loss of response to verbal commands or stimulation may be an indicator of loss of airway reflexes and respiratory/cardiovascular depression; thus sedation should be appropriately lightened
- 6) If an adverse event occurs at any given time, all staff must devote in immediate treatment and monitoring of patient until recovery, or until another RMP/RDP becomes available to take responsibility for patient's care.
- 7) Monitoring of patient should be continued throughout the recovery phase.

Documentation

Documentation of the following details should be done for all procedures and must be kept as part of patient's records

- a) Names of staff involved
- b) History, examination and investigation findings
- c) Dosages of drugs and their timings
- d) Vital signs pre, intra and post procedure

Recovery

Recovery should be carried out under appropriate supervision and monitoring in a properly equipped and staffed area.

Discharge

- 1) Discharge of patient should be authorised by the involved RMP/RDP who administered the drugs.
- 2) Patient must be discharged into the care of a responsible adult with instructions of care.

2.2 Drugs Usage For Procedural Sedation In The Emergency Department

Midazolam has become a common drug used for procedural sedation in emergency department in view of its short half-life, various routes of administration and less pain at injection site. It has anxiolytic, sedative, anti-epileptic, and muscle relaxant effects (Barzegari et al, 2015). Singh et al showed that use of intravenous Midazolam with 0.2mg/kg dose can induce adequate sedation with minimal side effects for paediatric imaging (Singh et al, 2009).

Propofol has become popular for use in emergency department due to its effective sedation and brief recovery (Gorchynski et al, 2006). It provides sedation, amnesia and anti-emetic effects; but not analgesia. In a randomised control trial done among adult patients in an urban county medical centre undergoing deep procedural sedation, patients were subdivided into propofol, 1:1 propofol/ketamine, and 4:1 propofol/ketamine groups. Highest percentage of overall sedation efficacy about 94.4% (85/90) derived from the 100% Propofol group. However, there was no significant difference in the frequency of adverse airway or respiratory events leading to intervention in either groups (Miner et al, 2014).

A study conducted among 40 subjects in Emergency Department Hospital Universiti Sains Malaysia comparing usage of Propofol and Midazolam in combination with Fentanyl showed no significant adverse events throughout the procedure in either groups. However the Propofol subgroup had shorter length of stay in the Emergency Department which is 29.25 min compared to 71.75min in the Midazolam group. (Nik N.A Rahman et al, 2011).

Ketamine is described as a unique drug for its hypnotic, analgesic, and amnestic effects on the same setting. As a result, it is favourable in procedural sedation in emergency department, particularly in paediatric emergencies (GAO et al, 2016). It is a dissociative drug where it acts by disconnecting the thalamocortical and limbic system (Alrabiah et al, 2016). A randomised control trial conducted in the United States assessed optimal dosing of intravenous Ketamine for procedural sedation in children in the emergency department. Among 171 children aged 3 to 18 years old enrolled, 125 of them received randomised doses of 1mg/kg, 1.5mg/kg, and 2mg/kg of IV Ketamine. It was concluded that adequate sedation was achieved with all 3 doses; and higher dose of 2mg/kg did not increase risk of adverse events or prolong sedation. (Kanikeswaran et al, 2016).

Current practice also involved use of Ketamine in conjunction with Propofol, called “Ketofol” in a single syringe mixture. It is used for adult procedural sedation, favoured for its opposing properties of each drugs; Ketamine mitigates Propofol induced hypotension, and Propofol mitigates Ketamine induced vomiting and recovery agitation (Green SM et al, 2011).

In ensuring safety administration of moderate sedation/analgesia, it is important for the doctors to have knowledge of the drugs to be of use in their procedures.

2.3 Rationale of study

Procedural sedation and analgesia (PSA) is part of the core services provided by the Emergency Department. Non anaesthetic doctors not only the emergency doctors are handling patients requiring these procedures and sufficient knowledge regarding drugs used and its side effects and good practice adhering to the guidelines available should be determined for patient's safety. As of current, the emergency doctors mostly the medical officers and postgraduate doctors are the one handling the PSA drugs while other doctors from disciplines involved carried out the intended procedures. Those who are frequently involved with PSA in the emergency departments apart from emergency doctors are the surgical based doctors.

The difference in knowledge of drugs used during the PSA and practices during the procedure are expected in these two subgroups; medical based and the surgical based. The outcome of this study is of benefit as to determine the need to provide formal and continuous training and assessment regarding procedural sedation and analgesia to the said group of doctors. A better structured protocol and reporting form is in hope to be created and acknowledged by all doctors involved so as to ensure patient safety and minimise risks and adverse events.

CHAPTER 3: RESEARCH QUESTION AND OBJECTIVES

3.1 Research Question

- 1) Is there a mean difference in level of knowledge and practice among medical and surgical non-anesthetic doctors involved in procedural sedation and analgesia in the Emergency Department?
- 2) What are the factors that influence the knowledge of procedural sedation and analgesia among non-anesthetic doctors in Emergency Department?

3.2 General Objective

To determine knowledge and practice of procedural sedation and analgesia among non-anesthetic doctors in the Emergency Department in HUSM.

3.3 Specific Objectives

- 1) To compare the mean of knowledge and practice level of procedural sedation and analgesia among medical-based and surgical-based non-anesthetic doctors in the Emergency Department.

- 2) To determine the factors that influence the knowledge of procedural sedation and analgesia among the non-anaesthetic doctors in Emergency Department.

3.4 Research Hypotheses

- 1) There is no difference in the level of knowledge and practice among medical and surgical non-anaesthetic doctors involved in procedural sedation and analgesia in Emergency Department.

- 2) There is positive correlation between demographic characteristics and level of knowledge of procedural sedation and analgesia among non-anaesthetic doctors in Emergency Department.

CHAPTER 4: METHODOLOGY

4.1 Study design

This is a cross-sectional study carried out from January 2013 to December 2014.

4.2 Target Population

All non-anaesthetic doctors involved in procedural sedation and analgesia in Emergency Department at HUSM.

4.3 Subjects

All non-anaesthetic doctors in Emergency Department, HUSM who have consented for this study were included at the time of data collection. All emergency doctors involved in procedural sedation and analgesia in Emergency Department including house officers, service medical officers, and postgraduate students in Emergency Medicine specialty were subjected for this research. They were either conducting the procedure or assisting it in the emergency department.

The non- emergency doctors involved in procedural sedation and analgesia from the medical-based specialty such as paediatric and internal medicine, and those from surgical-based specialty were surgery, orthopaedic, plastic or reconstructive surgery, general surgery, ENT, ophthalmology and dentistry.

The exclusion criteria are formally trained anaesthetic doctors and all emergency physicians as well as specialists and surgeons from the aforementioned specialties.

4.4 Sampling Method

All emergency doctors who were working in emergency department HUSM during the study period and fulfilled the inclusion and exclusion criteria were eligible for this research. They were approached while in their shifts and during formal teaching sessions in the department. The non-emergency doctors involved with the procedural sedation and analgesia for any procedures done in the emergency department were eligible once they consented for this particular study. As not many procedures were carried on a single appointed shift or time, some of the doctors were approached in their respective departments. All these doctors are divided into subgroups; medical based and non-medical or surgical based. Each groups consisted of equal amount of 72 samples, amounted to 144 subjects in total.

Once selected, they were briefed about the study procedures. Once they understood and agreed to participate they had to sign an informed consent. Then, the questionnaire forms were given to them for completion. See figure 1 depicting the brief study flow chart.

4.5 Sample Size Determination

The following formula was used (Cohen, J 1992) in calculating sample size for 2 main groups, medical-based and surgical based non-anaesthetic doctors.

α = significance criterion (taken as 0.05)

ES= population effect size

Calculated sample size for assessing knowledge is by using independent t-test, while for assessing practice using 2-proportion test (P difference). Calculation using 80% power with confidence interval of 95%. In estimating the sample size required to compare two proportions, the formula used is:

$$n = 16 p(1-p) / (p_1 - p_2)^2 \text{ where } p = (p_1 + p_2) / 2 ; p_1 = 0.1 \text{ and } p_2 = 0.3$$

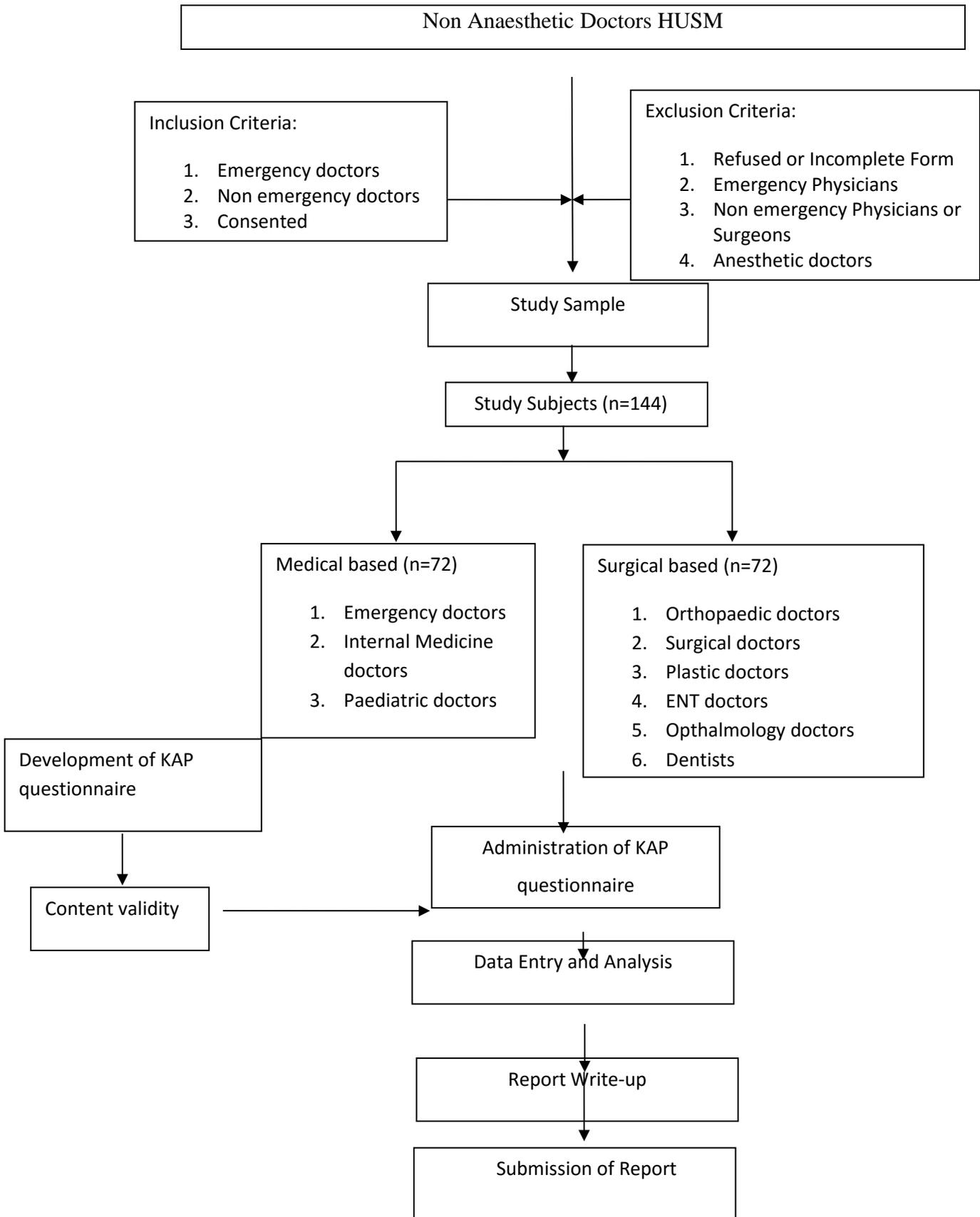
$$n = 16 (0.16) / 0.04$$

$$n = 64$$

Considering 10% dropout rate, hence amounted to 71 samples each group. Thus, the minimum amount of samples required is 142. In this study our collected sample are 144.

For determining factors associated with level of knowledge of procedural sedation and analgesia, 8 factors are identified, and by using multi linear regression, N for medium ES is 107 with significance of 0.05. The calculated sample is 119 in total number of samples.

Figure 1: Study Flow Chart



4.6 Research Tools and Questionnaire Development

A standardised and structured questionnaire was used in this study. It was a modified questionnaire from study done by Fanning in 2008 and used for this particular research.

This questionnaire is divided into 4 domains, the demographics, procedures, knowledge and practice regarding procedural sedation and analgesia. This is a self-reported questionnaire and subjects required not more than 10 minutes to complete it.

Demographics data were derived from each subject in the initial part of the questionnaire related to their age, sex, ethnicity, level of education, years in service, department of current service, and certification in Basic Life Support (BLS) or ACLS/PALS. Second domain questioned regarding procedures done in the emergency department and medications that has been used for the related procedures. This domain allow for multiple choices answers from subjects. The third main domain assessed the knowledge of drugs commonly used for PSA, whereby the correct answers resulted in 1 mark each totalling up to maximum 10 marks. The last but not the least important domain delved into the practices related to conducting and monitoring up to documentation of procedures done, and also availability of formal training and equipment preparation in anticipation of adverse events.

Questionnaire Development

The questionnaire that is used was suitable for the purpose of this study assessing knowledge and practice on procedural sedation and analgesia, and is derived from study by Fanning in 2008. However the validity of the questionnaire was not stated, not even in the subsequent study done by Priyan et al in 2011. The knowledge domain were assessed by a panel of experts consists of emergency physicians for content validation which required no statistical analysis and were accepted to be used for the actual study.

The questionnaires were then pre-tested as pilot study on a group of emergency doctors in HUSM who were not included in the actual study to assess for their ease of comprehension, relevance and effectiveness in providing useful information.. The reliability of the questionnaire on practice was analyzed by internal consistency using Cronbach alpha value. The analysis showed good internal consistency with acceptable correlation among items of 0.7-0.9. Therefore, very minimal modification was made to the questionnaire. (See Table 3.6.1)