A STUDY ON IDENTIFYING AND RESOLVING PROBLEMS ASSOCIATED WITH ADMINISTRATION OF DRUGS VIA NASOGASTRIC TUBE

A Project Report Submitted to

MANIPAL ACADEMY OF HIGHER EDUCATION

In partial fulfillment for the degree of Doctor of Pharmacy (Pharm D)

MANIPAL
ACADEMY of HIGHER EDUCATION
(Deemed to be University under Section 3 of the UGC Act, 1956)

Submitted By:

PRIYANKA PAI K
Reg. No: 170615004

SAMRIDDHI SHREE
Reg. No: 140614014

PharmD (PB) 2nd Year and Pharm D 5th Year
Department of Pharmacy Practice,
Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education,
Manipal.

APRIL 2019

Under the Guidance of:

Guide:
Dr. Sreedharan
Associate professor,
Department of Pharmacy Practice,
Manipal College of Pharmaceutical sciences,
Manipal Academy of Higher Education.

Co-Guide:
Dr. M Surulivel Rajan
Associate professor,
Department of Pharmacy Practice,
Manipal College of Pharmaceutical sciences,
Manipal Academy of Higher Education.

Co-Guide:
Dr. Shivashankar KN
Professor,
Department of Medicine,
Kasturba medical College,
Manipal Academy of Higher Education

MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

Certificate

This is to certify that this project report entitled **"Identifying and resolving problems associated with administration of drugs via nasogastric tube",** by **Ms.Priyanka.Pai.K,** and **Ms. Samriddhi Shree** for the completion of 2nd year PharmD (PB) and 5th year PharmD comprises of the bonafide work done by them in the Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and Kasturba Hospital, Manipal, under the guidance of, **Dr.Sreedharan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and co-guides **Dr. M.Surulivel.Rajan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and **Dr. Shivashankar KN,** Professor, Department of Medicine, Kasturba Medical College, Manipal Academy of Higher Education.

I recommend this piece of work for acceptance for the partial fulfilment of the completion of the 2nd year Pharm D (PB) and 5th year Pharm D program of the Manipal Academy of Higher Education, Manipal for the Academic year 2018-2019.

Dr. Sreedharan
Associate Professor,
Department of Pharmacy Practice,
Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education
Manipal – 576104
Karnataka, India
Place: Manipal
Date:

MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

Certificate

This is to certify that this project report entitled **"Identifying and resolving problems associated with administration of drugs via nasogastric tube",** by **Ms.Priyanka.Pai.K,** and **Ms. Samriddhi Shree** for the completion 2nd year PharmD (PB) and 5th year PharmD comprises of the bonafide work done by them in the Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and Kasturba Hospital, Manipal, under the guidance of, **Dr.Sreedharan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and co-guides **Dr. M.Surulivel.Rajan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and **Dr. Shivashankar KN,** Professor, Department of Medicine, Kasturba Medical College, Manipal Academy of Higher Education.

I recommend this piece of work for acceptance for the partial fulfilment of the completion of the 2nd year Pharm D (PB) and 5th year Pharm D program of the Manipal Academy of Higher Education, Manipal for the Academic year 2018-2019.

Dr. Mahadev Rao
M. Pharm, PhD
Professor and Head
Department of Pharmacy Practice
Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education
Manipal – 576104
Karnataka, India
Place: Manipal
Date:

MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

Certificate

This is to certify that this project report entitled **"Identifying and resolving problems associated with administration of drugs via nasogastric tube",** by **Ms.Priyanka.Pai.K,** and **Ms. Samriddhi Shree** for the completion 2nd year PharmD (PB) and 5th year PharmD comprises of the bonafide work done by them in the Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and Kasturba Hospital, Manipal, under the guidance of, **Dr.Sreedharan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and co-guides **Dr. M.Surulivel.Rajan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical sciences and **Dr. Shivashankar KN,** Professor, Department of Medicine, Kasturba Medical College, Manipal Academy of Higher Education.

I recommend this piece of work for acceptance for the partial fulfilment of the completion of the 2nd year Pharm D (PB) and 5th year Pharm D program of the Manipal Academy of Higher Education, Manipal for the Academic year 2018-2019.

Dr. M. Surulivel Rajan
Associate Professor,
Department of Pharmacy Practice,
Manipal College of Pharmaceutical sciences,
Manipal Academy of Higher Education
Manipal – 576104
Karnataka, India

Place: Manipal
Date:

MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

Certificate

This is to certify that this project report entitled **"Identifying and resolving problems associated with administration of drugs via nasogastric tube",** by **Ms.Priyanka.Pai.K,** and **Ms. Samriddhi Shree** for the completion 2nd year PharmD (PB) and 5th year PharmD comprises of the bonafide work done by them in the Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and Kasturba Hospital, Manipal, under the guidance of, **Dr.Sreedharan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and co-guides **Dr. M.Surulivel.Rajan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and **Dr. Shivashankar KN,** Professor, Department of Medicine, Kasturba Medical College, Manipal Academy of Higher Education.

I recommend this piece of work for acceptance for the partial fulfilment of the completion of the 2nd year Pharm D (PB) and 5th year Pharm D program of the Manipal Academy of Higher Education, Manipal for the Academic year 2018-2019.

Dr. Shivashankar KN
Professor,
Department of Medicine, KMC,
Manipal Academy of Higher Education
Manipal – 576104
Karnataka, India

Place: Manipal
Date:

MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

Certificate

This is to certify that this project report entitled **"Identifying and resolving problems associated with administration of drugs via nasogastric tube",** by **Ms.Priyanka.Pai.K,** and **Ms. Samriddhi Shree** for the completion 2nd year PharmD (PB) and 5th year PharmD comprises of the bonafide work done by them in the Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and Kasturba Hospital, Manipal, under the guidance of, **Dr.Sreedharan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and co-guides **Dr. M.Surulivel.Rajan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences and **Dr. Shivashankar KN,** Professor, Department of Medicine, Kasturba Medical College, Manipal Academy of Higher Education.

I recommend this piece of work for acceptance for the partial fulfilment of the completion of the 2nd year Pharm D (PB) and 5th Pharm D program of the Manipal Academy of Higher Education, Manipal for the Academic year 2018-2019.

Dr. C. Mallikarjuna Rao
M.Pharm, PhD
Principal
Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education
Manipal – 576104
Karnataka, India

Place: Manipal
Date:

MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

Declaration

We hereby declare that the project entitled, **"Identifying and resolving problems associated with administration of drugs via nasogastric tube"** was carried out under the guidance of **Dr. Sreedharan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal. The extent and source of information derived from the existing literature have been indicated throughout the project work at appropriate places. The work is original and has not been submitted in part or full for any diploma or degree purpose for this or any other university.

Priyanka.Pai. K
Reg No: 170615004

Samriddhi Shree
Reg No:140614014

Place: Manipal
Date:

Acknowledgment

"In the name of God, the Almighty, the most Generous and Merciful"

We express our utmost gratefulness to the almighty for the blessing throughout this study.

We are extremely thankful to our parents, grandparents, siblings, uncles, and aunts for giving us the opportunity to carry ourselves forward in the path of dream and for their unflagging love, care, attention, concern, and support throughout our life.

I humbly owe gratitude and sincere regards to my respected teacher and guide **Dr. Sreedharan,** Associate professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, for his valuable guidance, encouragement, untiring patience and support laid by him during all stages of our Work. His encouragement and fruitful suggestions have enabled to make our work worthy of presentation.

We extend our sincere and heartfelt thanks to **Dr. M. Surulivel. Rajan and Dr. Shivashankar KN** for their endless support and cooperation.

Special thanks to the nursing staff of Medicine ICUs', **Kasturba Hospital, Manipal** who have directly or indirectly helped us in the successful completion of this study.

Lastly, I offer my regards and blessings to all of those who supported us in any respect during the completion of the project.

LIST OF ABBREVIATIONS

API	Active Pharmaceutical Ingredient
CR	Controlled Release
Cyto	Cytotoxic
EC	Enteric Coated
ER/XR	Extended Release
FC	Film Coated
MR	Modified Release
NGT	Nasogastric tube
SL	Sublingual
SPSS	Statistical Package for the Social Sciences
SR	Sustained Release

LIST OF FIGURES

TABLE OF CONTENTS

LIST OF TABLES

LIST OF APPENDICES

ABSTRACT

ABSTRACT

Background: Administration of drugs via the nasogastric tube (NGT) has become very common in ICU patients. Many drug formulations are administered in the crushed form through the tube and this procedure is increasingly done by the nurses. Although crushing of solid dosage forms permits the ease of administration, there are several dosage forms that should not be broken or crushed as it can result in various problems like decreased or increased bioavailability, drug interactions or interaction with the tube itself.

Objectives: To assess the problems encountered when medications are being administered by nasogastric tube in a tertiary care hospital and to develop a guide/chart for medication administration by the NGT and to conduct a questionnaire survey among nurse practitioners to assess their knowledge on drug administration through NGT.

Methods: A prospective observational study was conducted in medicine ICU patients who were on nasogastric tube. Patient medical records were checked for the date of NGT intubation and the medications administered after the intubation. The drugs administered were checked for appropriateness of the dosage form. A questionnaire study was conducted among the nurses to assess their knowledge regarding the administration of drugs through the NGT. Data entry and statistical analysis were done using the software version of SPSS 20.

Results: Out of a total of 261 drugs administered to the patients with nasogastric tube, 68.1% of the medications were found being administered through the tube and the remaining 31.8% of the drugs were administered through other routes. Among the 178 drugs administered through the tube, it was found that 48.87% of the drugs were being administered inappropriately, that is, drugs of the dosage forms that must not be crushed were found being crushed and administered and 51.12% drugs were administered appropriately. The questionnaire survey had a response rate of 62.5%. While 90% of the nurses agreed to assess the dosage form before administering it through the NGT, only 20% were aware that SR/CR tablets should not be crushed and 57.5% were aware that enteric coated drugs must not be crushed before administration. A total of 80% of nurses agreed to pursue continuous education regarding appropriate administration of drugs through the NGT.

Conclusion: Potential problems associated with the administration of inappropriate dosage form of drugs through the NGT are great many. It can lead to drug interactions, increased or decreased bioavailability or adverse reactions which may be fatal to patients. Nurses have to be vigilant about the dosage forms they are administering. An increase in awareness regarding medication prescription among clinicians is of utmost importance. Clinical pharmacists can be of great assistance with regards to prescription monitoring, thus helping in reducing the clinicians as well as the nurse's burden.

INTRODUCTION

1.INTRODUCTION

Enteral nutrition is the key method for the administration of food and drugs in critically ill patients. Enteral feeding is usually recommended in patients who are having difficulty in swallowing or are unable to swallow, have facial or esophageal structural abnormalities, anorexia related to chronic illness, eating disorders, increased nutritional requirements, congenital anomalies or for primary disease management [(1)]. Nasogastric tubes (NGT) are usually used in hospitals for the purpose of enteral feeding. NGT can be used in the administration of feeds, either bolus, continuous or intermittent, for the administration of medicines, for free drainage and aspiration of stomach contents and to facilitate venting or decompression of the stomach[(1)]. The need for taking proper precautions while administering drugs concurrently through the NGT is profuse as it may result in various complications such as diarrhea, tube occlusion and lack of therapeutic efficacy[(2).]

While there are many reasons which indicate that the crushing of medications is necessary, there are some pharmaceutical dosage forms that should not be crushed as it might result in loss of drug pharmacokinetic properties rendering the drug therapeutically ineffective. Some of the dosage forms that should not be crushed are those that have an enteric coating. This kind of coating is present on drugs which are inactivated by gastric acid, or that could irritate gastric mucous and delivery of the drug occurs in the intestinal region. Drugs which are of the sublingual form should also not be crushed since they are meant to dissolve in the mouth quickly and reach the bloodstream fast. Sugar-coated tablets serve the purpose of masking bitter taste and also to protect from light and humidity. Soft gelatin capsules (with liquid content) should also not be chewed or split, since the extraction of the liquid inside may lead to incorrect dosage. Medications which are prolonged/sustained/controlled release are designed in such a way so as to deliver the required amount of dose at the required or specific rate and at the specific time. The crushing of these dosage forms leads to the destruction of the coating present which might, in turn, lead to various other problems such as increased or decreased bioavailability of the drug which might cause bigger problems and can also at times be fatal. Another category of drugs which might cause harm to destruction is the cytotoxic drugs crushing these might not vary their physicochemical properties. But it can be very harmful to the person preparing these suspensions due to the nature of the drug[(3)]. Active pharmaceutical ingredients (API) like levothyroxine have small therapeutic windows[(4)]; that is to say if split into uneven parts and ingested, elevated doses of the medication are obtained for immediate absorption and can potentially cause toxicity, or result in a dosage which is under the therapeutic dose.

There are various guidelines which direct the health care professionals towards more responsible administration of drugs via the nasogastric tube (NGT). The American Society for Parenteral and Enteric Nutrition, also called as the ASPEN Guidelines is the most widely used guideline for reference while administering drugs through the enteral route[(5)]. It is extremely important to adhere to the guidelines during enteric medication administration as there are a lot of chances of the occurrence of improper drug administration.

The nurses, who are the medical staff who are usually responsible for providing enteric nutrition to patients, should be thoroughly aware of the steps to be followed for enteric administration and should be skilled enough to administer enteric feeding properly in order to achieve the required effect which is being sought.

While there are clinical guidelines which have been established for provision of ideal enteric nutrition, there is still a lack of knowledge among the health care professionals relating to the pharmaceutical dosage forms which are not to be crushed before administration and this may result in therapeutic failure and hence, may result in causing more harm than good to the patient.

This study was conducted in order to identify and resolve potential problems which might arise due to the administration of drugs vis the nasogastric tube and to check the knowledge of nurses regarding the administration of drugs via the NGT.

NEED FOR STUDY

2.Need for study

Dysphagia, that is, difficulty to swallow is one of the most common problems in patients who are critically ill. Oral route being the most favored route for solid dosage form administration, can still cause problems when patients are not able to swallow them down easily enough since there is a probability of the tablet getting stuck in the throat. Hence, they are crushed and administered through the nasogastric tube in order reduce the patients' discomfort but at the same time, provide them with the care which is needed for them to get better, in the form of medications and nutrition.

Crushing of tablets/splitting of capsules provides an easier way for administration in patients with difficulties to consume the drug orally, but it also brings about a lot of issues regarding the drug itself as the crushing or splitting may bring about changes in the drug pharmacokinetic and pharmacodynamic properties.

Administration of oral medications have been problematic in admitted Intensive Care Units (ICU) patients(6). Some of the main errors which might occur while administering drugs through NGT are incompatibility of the route, improper drug absorption, improper preparation of drug suspension which is to be administered and using wrong drug administration techniques.

A drug has various physical and chemical properties which need to be considered by the health care professionals before prescribing/administering them through the nasogastric tube (NGT). Administering drugs through the enteral route may lead to the destruction of drug properties and maybe harmful. It is extremely important to make sure that the suspensions are prepared in a proper way. Any normal tablets being crushed should be crushed thoroughly, without leaving behind any masses or coating remnants. The tablets should be made into a smooth uniform powder and then they should be suitably diluted. Capsules must be opened and the contents diluted properly. If the syrups are viscous, then should be diluted and the dose adjusted accordingly.

While crushing uncoated tablets might not cause any changes in the drugs' bioavailability, there are certain preparations/dosage formulations that must not be crushed as it will lead to the destruction of the coating which is present to serve a particular purpose for the drug that has been formulated that way. Enteric coated drugs are drugs which have an external surface coating which prevents the drug from the acidic environment of the stomach and only allows it to dissolve once it reaches the intestine. Sustained release tablets have a coating membrane which allows for controlled release of drug in the required amount at the required time.

Crushing of these tablets will destroy the coating which has an important role to play in the drug delivery to the body, causing either the destruction of the drug before it reaches the site of action or a drug dump, where the drug is released into the body all at once, instead of in controlled amounts, which might lead to the occurrence of adverse events. Capsules containing sustained release or enteric coated pellets must not be crushed. Soft gelatin capsules must not be opened as it may lead to loss of the drug since the complete transfer of the contents cannot be guaranteed. Sometimes the excipients present in the capsule may cause clogging of the tube and lead to incomplete delivery of the drug. They may also increase the viscosity or osmolality of the solutions which might lead to further complications.

A proper and uniform administration technique should be followed in order to avoid complications which might occur due to improper administration of drugs. Nurses are mostly the healthcare professionals who are involved in the administration of drugs through the NGT and they mostly rely on their as well as their seniors' experience to administer the drugs. This causes variation in technique among different people, leading to non-uniformity. Most of the times, a crusher is used to crush the tablets and if only single equipment is used to crush all the tablets and if the crusher is not cleaned properly between uses, the drugs might interact and affect the efficacy. There are possibilities of drugs binding to the enteric feeding tube and the proper amount of drug not being delivered to the body. Crushing of drugs might be dangerous to the healthcare professionals themselves as some drugs are carcinogenic and might cause skin irritation and other harmful health hazards to the administrator(7).

Other complications of crushing a tablet/splitting a tablet is that upon crushing, the tablet comes in contact with air, light, humidity which might negatively affect its efficacy and disturb its stability. Chemical interactions and contamination might occur when the drugs are crushed.

Although there are guidelines in place about proper and careful administration of drugs through the nasogastric tube, there is a dearth lack of knowledge among the healthcare professionals about the appropriateness of the dosage forms which should or should not be crushed administered through the NGT. Administration of inappropriate dosage forms by crushing might lead to more problems for the patient. Prescription of drugs to be administered through the NGT needs close monitoring.

AIMS & OBJECTIVES

3.0 Aims:

To identify and resolve the problems arising due to the administration of drugs through the nasogastric tube.

3.1 Objectives:

1. To assess the problems encountered when medications are being administered by nasogastric tube in a tertiary care hospital and to develop a guide/chart for medication administration by the NGT.

2. To conduct a questionnaire survey among nurse practitioners to assess their knowledge of drug administration through NGT.

METHODOLOGY

4.METHODOLOGY

4.1 Study Site: The study was conducted in ICU's of Kasturba Hospital, Manipal.

4.2 Study design: Prospective observational study.

4.3 Study period: 12 months (Sept 2018 – Sept 2019)

4.4 Sample Size: All Medicine ICU patients with NGT during the study period.
Questionnaire administered: 61

4.5 Ethical Approval:
The protocol for this study was approved by the Institutional Ethical Committee of Kasturba Hospital, Manipal. (IEC/568/2018)

4.6 Study criteria:

4.6.1 Inclusion criteria:
All patients admitted in Medicine ICU's with NGT
Patients of both gender on NGT.

4.6.2 Exclusion criteria:
Pediatric patients.
Files with incomplete data.
Patients admitted in Medicine ICU 1 and other ICUs.

4.7 Data source:
All the necessary and relevant data were obtained from the medical records of patients intubated with a nasogastric tube and from hospital pharmacy database. Questionnaires were given to nurses to assess their knowledge of administration of drugs through the NGT.

4.8 Study materials:

- ✓ Participant Information Sheet (PIS) - Used to provide necessary details (purpose, benefits/risks, procedure) regarding the study.
- ✓ Informed Consent Form – An Informed consent form in Kannada or English was obtained from each participant/ LAR before study initiation.
- ✓ Case Report Form (CRF) - To collect patient data (demographics, drug treatment chart, etc.).
- ✓ Questionnaire – To collect information regarding Nurses' knowledge of administration of drugs through the NGT.

4.9 Operation modality:

Kasturba Hospital, Manipal is a 2000 plus bedded tertiary care hospital. The patients on NGT were identified through the movement of the nasogastric tubes from the pharmacy. This information was identified from the pharmacy database. The relevant patient information required for the study such as age, gender, body weight, past medical history, past medication history, clinical diagnosis, co-morbidities, and medication details such as dose, duration and frequency, route of administration and concomitant drugs were collected from the above listed sources and documented in the suitable data collection form which was designed for the study (CRF). A survey was also conducted among the nurses working in the ICUs', for which purpose, a questionnaire was designed.

The patients' medical charts were reviewed for the medicines that were being administered through the NGT. The drugs administered were grouped based on whether or not they had any coating and whether or not it was appropriate to crush them. Alternatives were suggested wherever possible to aid the non-crushing of medicines which have special coatings. The data collected from the questionnaire was used to assess the nurses' knowledge regarding inappropriate crushing of drugs and the administration of drugs through the NGT.

4.10 Statistical Analysis

Frequency and Percentage (%) are used to summarize the categorical variables. All statistical analysis was carried out using SPSS version 20.

RESULTS

5.Result:

To identify the problems associated with administration of drugs through the nasogastric tube, patient records were checked for appropriateness of drug dosage forms while being administered through the NGT, it was found that there were certain dosage forms which were administered through the tube, which were not ideally supposed to crushed due to the presence of various kinds of coatings present on the drugs. Normal uncoated tablets are ideal for crushing and administering through the tube and crushing these tablets will not in any way affect their bioavailability, although, other factors like the interaction with other drugs and the feed being administered through the tube and the interaction of the drug with the tube itself should be considered and checked thoroughly. While crushing won't drastically affect an uncoated tablets' bioavailability, it varies the release patterns of several other dosage forms, which have coatings specially designed for controlling the extent of their release and also control when and where a drug should be exactly released to get the maximum benefit. Table 1 indicates different kinds of drug dosage forms and the particular reasons why such a dosage form should not be crushed.

Abbreviation	Meaning	Details on crushing
S/C, F/C	Sugar- coated, Film-coated	Usually coated for improving the appearance, masking the taste or protecting them from light and humidity. Maybe crushed but crushing can cause the drugs to react with light/humidity and may result in the loss of drugs. Also, the coating may clog the feed tube. Hence, if these tablets are crushed, then it should be made sure that the coating is properly crushed and should be administered immediately. The feeding tube should be flushed well after use.
EC, EN	Enteric-coated	Enteric coating to a tablet provides the dissolution of the drug in the stomach and promotes its absorption in the small intestine. Upon crushing, these tablets may cause stomach irritation and decreased drug effectiveness. They may also clog the feeding tube.
SR, ER/XR, MR, CR	Sustained release/Slow release, Extended-release, Modified release, Controlled release	These drugs are intended to be released gradually over time, and often have a special coating to enable this. If the tablet is crushed and passed down the enteral feeding tube, an increase in the expected peak plasma level may occur ("dose-dumping"). The patient will be

		initially exposed to significantly higher-than-normal levels which will increase the chance of side effects. Later, the drug will not last the full dosage interval, resulting in a period with little or no drug present, possibly resulting in loss of control of the patient's condition. Modified-release preparations are also unlikely to disperse completely when crushed, leading to an increased risk of tube occlusion.
SL	Sublingual/Buccal tablets	Drugs formulated in these dosage forms are designed not to pass through the stomach in order to avoid the first pass metabolism effects in the liver. If these tablets are passed down the enteral feeding tube, drug effect will be decreased.
Cyto	Cytotoxic	All staff should avoid contact with cytotoxic drugs. There is a risk of cytotoxic powder being aerosolized if cytotoxic tablets are crushed, exposing staff to hazardous materials. Cytotoxics should be handled in accordance with local procedures.

Table 1: Drugs that ideally should not be crushed(8)**.**

According to the data obtained during the study period, it was found that certain dosage forms were being crushed before administration, irrespective of the fact that they should not be crushed. Out of a total of 261 drugs prescribed during the study time to the patients admitted in the Medicine ICUs of the hospital, one hundred and seventy-eight (68.19%) of the drugs were administered through the NGT. The drugs administered through the NGT included tablets, capsules, and syrups. 31.80% that is eighty-three drugs were administered through other routes which did not pose any problems associated with NGT because they are not administered through the enteral route.

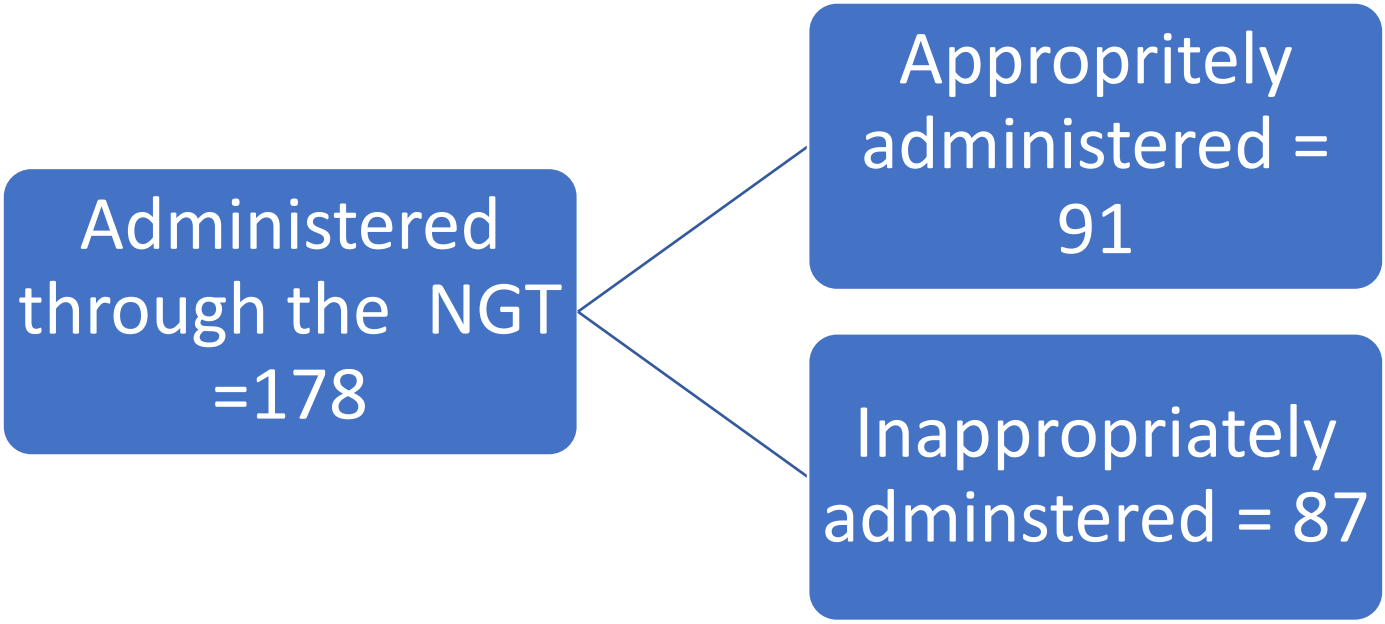

Figure 1: Flow-chart depicting drug distribution in patients admitted to Medicine ICUs with NGT.

Among the one hundred and seventy-eight drugs that were administered through the NGT, it was found that ninety-one drugs, that is, 51.12 % of the drugs were administered appropriately. This number constituted of uncoated tablets, sugar-coated tablets, capsules, and syrups. The remaining 48.87% (eighty-seven) comprised of drugs which were inappropriately administered. This consisted of drugs which were either film coated, enteric coated, sustained release, controlled release cytotoxic in nature. The 87 drugs consisted of 73.56 % of film coated drugs, 21.83% of enteric coated drugs, 2.29% of sustained release drugs, 1.14% of control release and 1.14% of cytotoxic drugs. Table 2 depicts the drugs which were administered via the nasogastric tube in patients admitted to Medicine ICUs with NGT and its appropriateness.

Pharmaceutical Dosage Form (n)	Active Ingredient(n)	Tube administration appropriate	Tube administration inappropriate.
Tablets/Capsules (77)	Folic Acid (4) Amlodipine (3) Clobazam (2) Thyronorm (2) Acebrophylline (1) Tolvaptan (2) Lanoxin (1) Paracetamol (6) Ramipril (1)	77	-

	Aldactone (1) Torsemide (1) Amiodarone (4) Ethamsylate (1) Furosemide (2) Rifampin+Isoniazid (2) Pyrazinamide (3) Ethambutol (3) Pyridoxine (2) Doxofylline (2) Isosorbide Mononitrate (1) Vitamin C (1) Lactic Acid (1) Isoniazid (1) Aspirin + Atorvastatin (10) Multivitamin (7) Phenytoin (2) Multivitamin (1) Aspirin+Atorvastatin+Clopidogrel (2) Dabigatran (1) Multivitamins (3) Oseltamivir (3) Methyl Prednisone (1)		
Film Coated (64)	Atorvastatin (7) Thiamine (5) Clopidogrel (7) Amlodipine (5) Citicoline (1) Sodium Bicarbonate (2) Quetiapine (1) Levetiracetam (9) Azithromycin (5) Clarithromycin (1) Sildenafil (1) Spironolactone + Furosemide (2) Ivabradine (7) Febuxostat (2) Rifaximin (1) Vitamins (1)	-	64

	Lacosamide (1) Calcium + Calcitriol (1) Acetaminophen + Tramadol (2) Domperidone (2) Desloratadine (1)		
Enteric coated (19)	Pantoprazole (14) Aspirin (5)	-	19
Sustained release (2)	Rabeprazole + Domperidone (1) Isosorbide Mononitrate (1)	-	2
Control release (1)	Sodium Valproate (1)	-	1
Cytotoxic (1)	Hydroxyurea (1)	-	1
Syrup (14)	Lactulose (4) Vitamins (1) Piracetam (2) Lactitol + Benzoic Acid (2) Potassium citrate + Magnesium citrate (2) Sodium Picosulfate + Liquid Paraffin + Milk of Magnesia (1) Ambroxol + Guaifenesin + Terbutaline (1) Levetiracetam (1)	14	-
Total	178	91	87

Table 2: Drugs that were administered through the Nasogastric tube

One of the solutions that can be suggested to solve the problem arising due to administration of inappropriate dosage forms is the suggestion of alternate dosage forms. The most suitable alternatives for drugs with special coatings are uncoated drugs, dispersible tablets, injections, suspensions or syrups. The dose will have to be adjusted with respect to the bioavailability and pharmacokinetics of the dosage form which is chosen as the replacement to match with the dosage and release patterns of the coated drugs. In our study, a total of 21 film-coated tablets, 2 EC, 2 SR, 1CR and 1 cytotoxic drug were found, which are the dosage forms that should not be crushed. Out of the 27 drugs, alternatives were found to exist for 20 drugs. Table 3 depicts a guide/chart of the drugs with coatings which made them unsuitable for crushing in our study population, for which alternatives were found.

Active Ingredient	Coating	Available alternative
Amlodipine	FC	Uncoated Tablet
Citicoline	FC	Injection, Syrup
Sodium bicarbonate	FC	Injection

Pantoprazole	EC	Injection
Quetiapine	FC	Injection, Syrup
Levetiracetam	FC	Injection, Syrup
Sodium valproate	CR	Injection, Syrup
Rabeprazole + Domperidone	SR	Rabeprazole-Injection, Domperidone-Syrup
Azithromycin	FC	Suspension, Injection
Clarithromycin	FC	Injection
Sildenafil	FC	Suspension
Spironolactone + Furosemide	FC	Separate injections available
Isosorbide mononitrate	SR	Uncoated tablet
Ivabradine	FC	Injection
Rifaximin	FC	Injection
Vitamins	FC	Injection
Acetaminophen + Tramadol	FC	Separate injections available
Domperidone	FC	Syrup
Desloratadine	FC	Dispersible tablets
Aspirin	EC	Dispersible tablets

Table 3: Inappropriate dosage forms and their available alternatives.

The second part of this study consisted of a questionnaire survey which was conducted among the nurses working in the Medicine ICUs of the hospital to find out about their knowledge regarding medication crushing and administration of medicines through the NGT. The response rate for this survey was found to be 62.5%. Among the nurses, 20% were aware that Sustained Release or Control release tablets are not supposed to be crushed. 57.5% reported that the crushing of Enteric coated drugs is not appropriate. Overall 90% of nurses assessed the appropriateness of the dosage form of drugs before administering through NGT. 62.5% of nurses were aware that certain pharmaceutical dosage forms should not be crushed or opened.

The second part of this study consisted of a questionnaire survey which was conducted among the nurses working in the Medicine ICUs of the hospital to find out about their knowledge regarding medication crushing and administration of medicines through the NGT. The response rate for this survey was found to be 62.5%. Among the nurses, 20% were aware that Sustained Release or Control release tablets are not supposed to be crushed. 57.5% reported that the crushing of Enteric coated drugs is not appropriate. Overall 90% of nurses assessed the appropriateness of the dosage form of drugs before administering through NGT. 62.5% of nurses were aware that certain pharmaceutical dosage forms should not be crushed or opened. 40% of nurses admitted to administering the medications via NGT all at once. 62.5% flushed the tubing after individual usage of a drug. 87.5% of nurses know the problems arising with the concurrent NGT drug administration. 80% of nurses use the tablet crusher for crushing the drugs. 72.5% of nurses prepare a proper suspension of the drug before administration. 75% consult a doctor or a pharmacist in case of any guidance regarding the drug administration. 80% of nurses agreed to attend Continuous Educational programs informing about the administration of drugs through NGT. Table 4 gives an overview of the results obtained from the questionnaire survey. Figures 2-12 represent the various answers given by the nurses for the questions asked in the questionnaire.

ITEMS	DATA
Percentage of nurses who are aware about the inappropriateness of crushing SR/CR tablets	20%
Percentage of nurses who are aware about the inappropriateness of crushing enteric coated drugs	57.5%
Percentage of nurses assessing appropriateness of dosage form of drugs before administering through NGT	90%
Percentage of nurses who are aware of the fact that certain tablets/capsules shouldn't be crushed/opened	62.5%
Percentage of nurses who administer medications all at once through NGT	40%
Percentage of nurses who wash the pipe between administration of different drugs	62.5%
Percentage of nurses who are aware of the problems associated with concurrent administration of drugs through NGT	87.5%
Percentage of nurses using tablet crusher to crush the drugs	80%
Percentage of nurses who prepare suspensions for NGT administration	72.5%
Percentage of nurses who consult a doctor or pharmacist for help	75%
Percentage of nurses who would like to attend CE programs about administration of drugs via NGT	80%

Table 4: Data derived from questionnaire concerning nasogastric administration and crushing of tablets

Results of the questionnaire survey conducted.

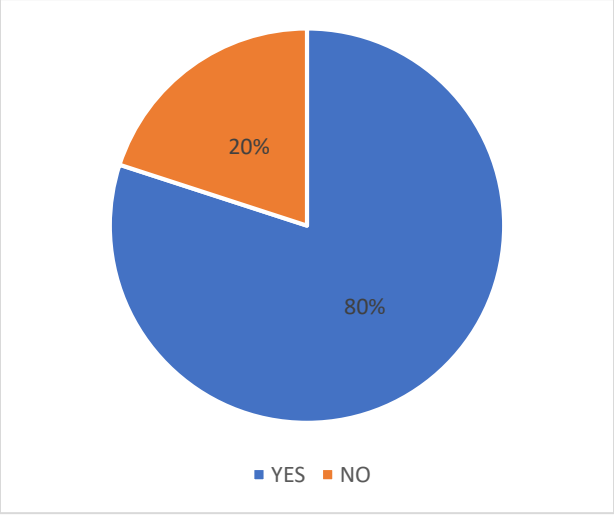

Figure 2: Appropriateness of crushing SR/CR coated tablets before administration.

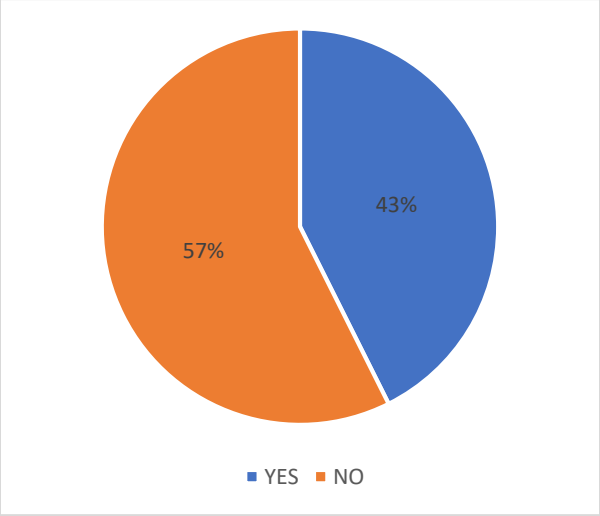

Figure 3: Appropriateness of crushing enteric tablets.

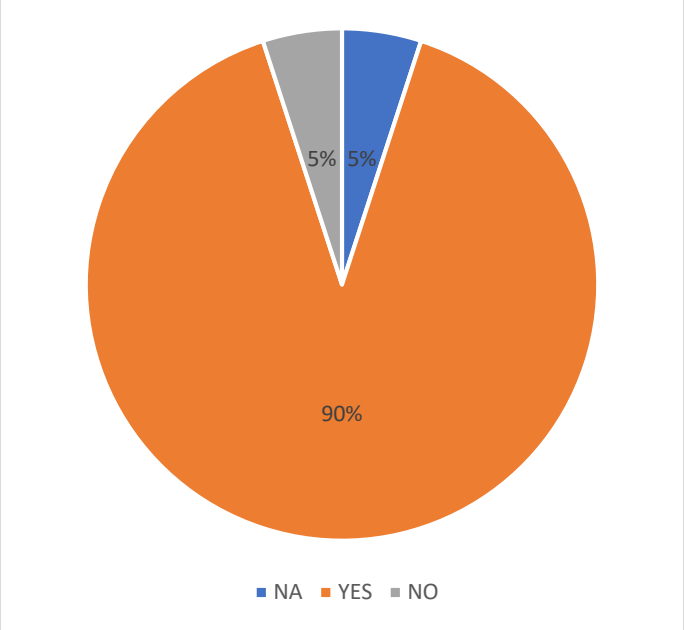

Figure 4: Assessment of appropriateness of dosage forms of drugs before administering through NGT.

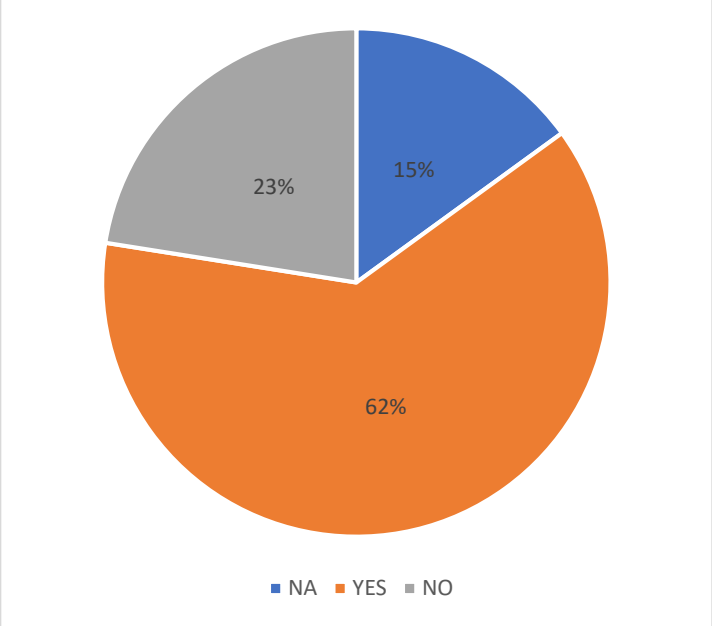

Figure 5: Awareness of the fact that certain tablets should not be crushed/opened.

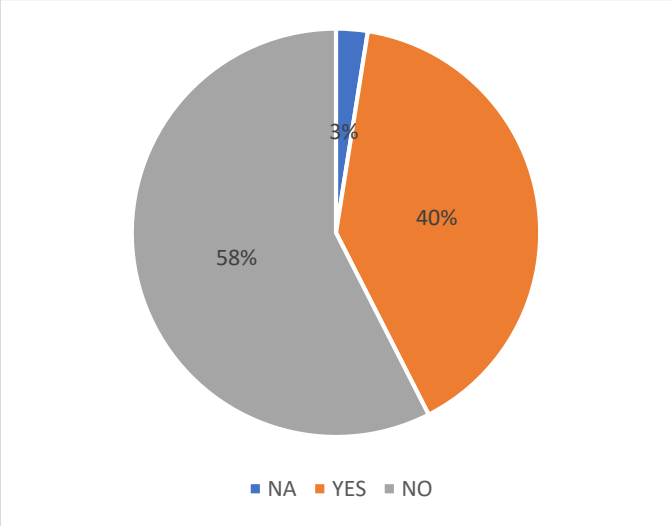

Figure 6: Administration of all the medications at once through the NGT.

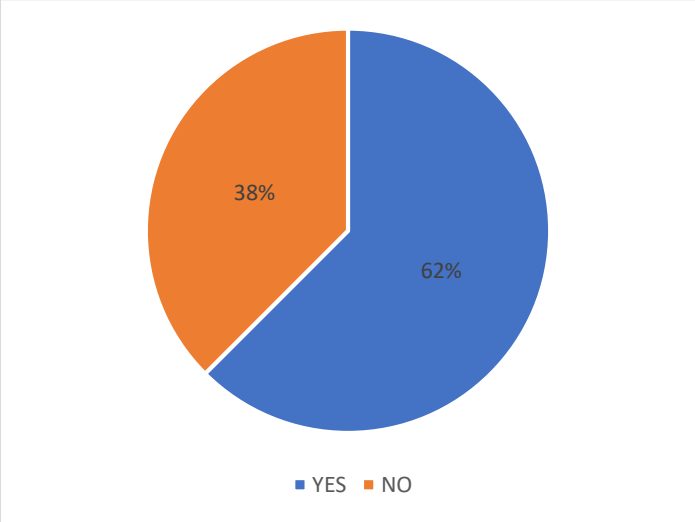

Figure 7: Wash the pipe between administration of different drugs.

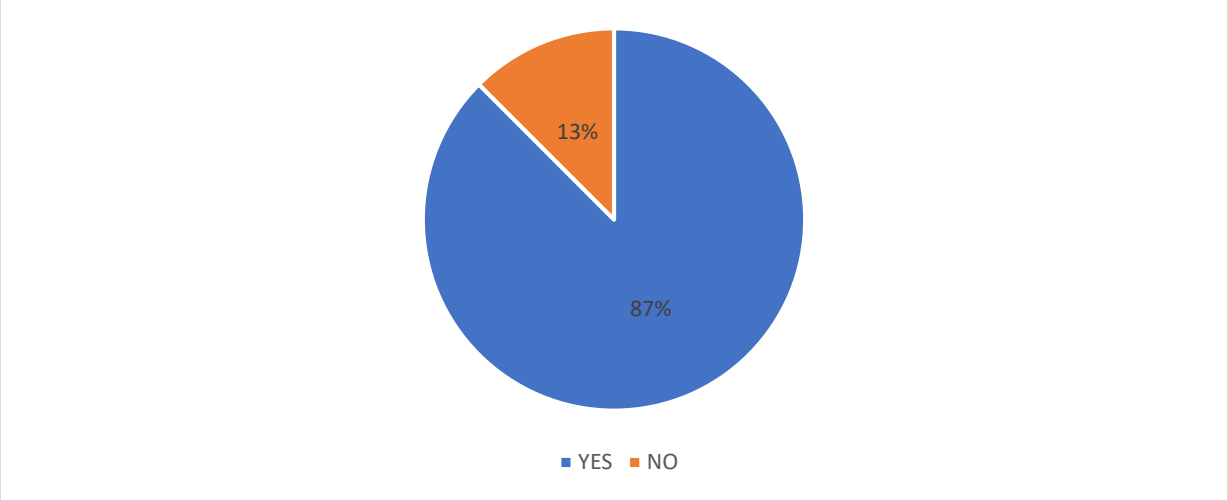

Figure 8: Awareness of the problems associated with concurrent administration of the drugs through NGT.

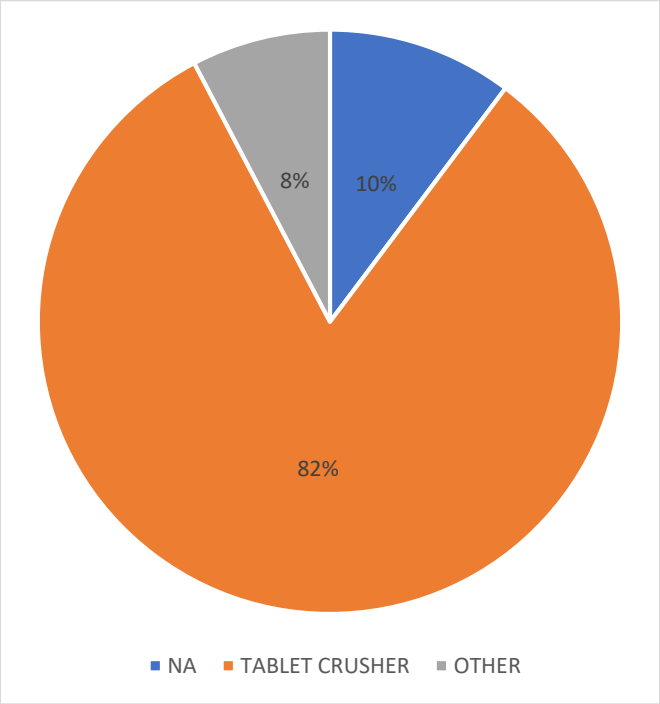

Figure 9: Methods used to crush the medication before administration through NGT.

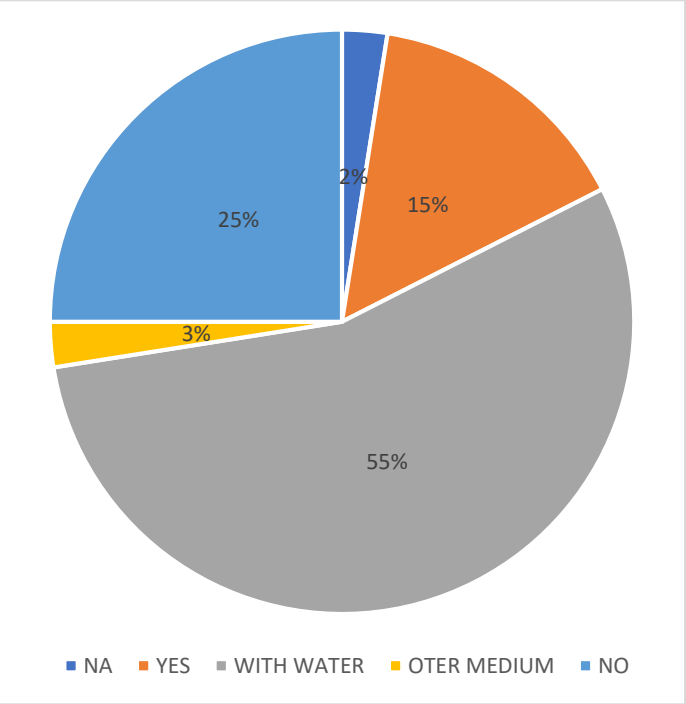

Figure 10: Preparation of suspension of the medicine before administering it through the tube and the medium used for preparing the suspension.

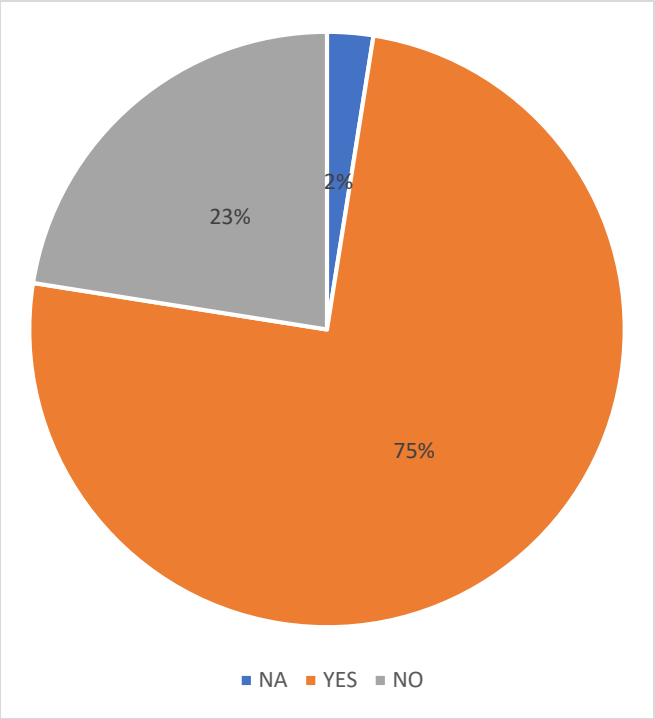

Figure 11: Taking help from the doctor or pharmacist regarding administrations of medications through NGT.

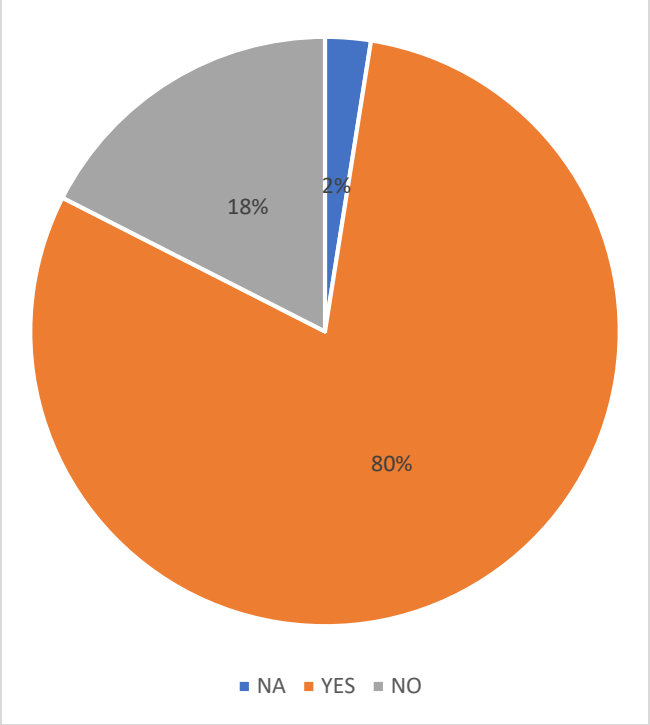

Figure 12: Interest in attending CE programs on administration of drugs through NGT.

DISCUSSION

6. Discussion:

The result of our study reveals that certain drugs which were administered through the tube were not ideally supposed to crushed due to the presence of various kinds of coatings present on the drugs. Out of the drugs being prescribed during our study period in the medicine ICUs, 68.1% of drugs were prescribed via NGT and 31.80% of the drugs were administered either parenterally or through nebulization. 51.41% of the drugs given by NGT were administered appropriately. The remaining 48. 58% comprised of inappropriately administered drugs. Our study can be compared to a similar study conducted by K Demirkan et al[(2)]., where around 40% of the drugs were found to be inappropriately administered.

Unlike the study done by Rose Ngozi Mafianaa, et al(9), that focuses on the difference in Inappropriate administration of the drugs between a case and a control group, before and after educational training, our study only focuses on the current knowledge of the nurses i.e. without any educational program. In the case of that study, Nurses' showed improved performance in the case group after the information provided.

Our study also focuses on Nurses' knowledge of the crushing of drugs. It was found that crushing of tablets is a fairly common practice among the nurses in our hospital. In an observational study by Stubbs et al(10). on medication administration to psychiatric patients in a hospital in the UK, reported that 25.5% of prescribed oral solid doses were crushed or opened. Similar findings were also reported by Belknap et al. (11), Wright D(12)., and Paradiso et al(13).

Nurses (76.5%) admitted they regularly crushed oral solids as per a study done by Rose Ngozi Mafianaa, et al(9),.Similarly, Nissen and colleagues found that among nurses who administered medications in local public hospitals in Australia, 75% crushed tablets.

The second part of our study consisted of a questionnaire survey which was circulated amongst the nurses working in the Medicine ICUs of the hospital to find out about their knowledge regarding medication crushing and administration of medicines through the NGT. 62.5% of nurses chose to respond to the questions. The response showed moderate knowledge amongst the nurses about the tablet coating. Though the majority of nurses (90%) are aware that there are some specially formulated oral solids that should not be crushed, only 20% could correctly indicate how they would recognize all such special formulations. Thus, exposing the patients to the potential risks associated with such a practice.

A study conducted by Hanssens et al(14)., reported that the ability of nurses to recognize coding for specially formulated tablets that should not be crushed increased from 0% to 30% after a 2-day awareness training regarding the crushing of tablets. Other studies also showed the benefits of awareness training. Our study also aims to provide the required knowledge to the nurses regarding the crushing of the medications.

In another study conducted by Mota M et al(15)., it was reported to that about 36.7 % disregarded the dosage forms provided by the pharmacy and only 28.6% of them were able to identify sustained release drugs to belong to the category of drugs which should not be crushed. When these results are compared to our study, we can see a significant increase (90% of the nurses) in the number of nurses who did assess the appropriateness of the dosage form being administered. But the nurses with the awareness that sustained release drugs must not be crushed comparatively remained same (20% of the nurses as compared to 28.6% of them in the study conducted by Mota M et al.,)

In a study conducted by Dashti-Khavidaki et al(16), they hinted at the importance of the role clinical pharmacists might play in improving nurse's knowledge regarding enteral administration and about the appropriateness of dosage forms before crushing it for NGT administration. They also suggested developing a proper universal guideline regarding enteral administration so that there is uniformity in administration techniques and the nurse's knowledge. According to them, the guidelines should also be a part of the curriculum for clinicians during their study, so that it can provide them with the required knowledge to prescribe appropriate dosage forms for people with NGT.

Although there are guidelines and defined steps regarding proper administration of drugs through the NGT, there is an immense lack of knowledge among the health care professionals with respect to prescribing and administering drugs through the NGT. There is a lack of educational courses which teach enteral administration in detail. Clinical pharmacists can play an important role in improving the current status of the situation since they are aware of various dosage forms and their appropriateness regarding crushing them. Most clinicians and nurses are not aware of the role clinical pharmacists can play in monitoring prescriptions and thus rendering their services in decreasing the clinicians' and nurse's workload and can also help in avoiding adverse effects and drug interactions which might possibly occur. Continuous education programs regarding enteral administration will play an important role in improving the knowledge of health care professionals and make them more aware of the criticality of the issue. Better communication between all the health care professionals including the doctors, nurses and the pharmacists and them working together can lead to solving a lot of problems which arise due to improper medication prescription and administration.

LIMITATIONS

7.LIMITATIONS:

- ✓ The study was only conducted in the Medicine ICUs and patients from other wards with NGT weren't taken into account.
- ✓ Drugs that were administered during the study period were only considered during analysis which may have led to exclusion of drugs which are not suitable for crushing but might not have been prescribed during the study period.
- ✓ The sample group chosen for the questionnaire study was relatively small and hence the findings from the study cannot be generalized.
- ✓ Not all questionnaire forms were answered completely, leading to missing data and inconclusive results
- ✓ The answers provided by the nurses for the questionnaire may not always be what they actually practice in real-life situations.
- ✓ The number of patients obtained during the study period was few leading to small sample size.
- ✓ The short period of time and a limited number of samples for the questionnaire study might have led to bias in our findings.

CONCLUSION

✓ .

8.CONCLUSION:

The crushing of medications for administration through the NGT is a very common practice among critically ill patients or among those who have difficulty in swallowing due to other illness. Even though this aids to ease of administration, it is not always right to crush the medications without considering their dosage forms. In our study, we found that a lot of the dosage formulations that must not be crushed due to the presence of certain coatings for various reasons are being crushed so that they can be administered via the NGT. The nurses, even though, had a fair knowledge about inappropriate medication crushing, can still be more vigilant about the drugs being administered and the method of administration as well as the cleanliness of the tube itself. It is also important that the clinicians must be careful while prescribing drugs which might not be appropriate for administration through the tube. All aspects of the delivery of the drug to the system must be properly assessed before prescribing. Involvement of clinical pharmacists can be considered for the purpose of prescription monitoring, which might help unburden the clinician as well as the nurses. There are not many studies which are conducted regarding the assessment of problems caused by inappropriate crushing of drugs for tube administrations. Our study will help in understanding such problems better and trying to find solutions for them, hence limiting patient harm and causing improvement of patient health and their quality of life.

FUTURE DIRECTIONS

9. FUTURE DIRECTIONS:

1. A study on all the dosage forms that should not be crushed can be conducted and a list can be made and supplied to all the departments/units in the hospitals.
2. Continuous education programs regarding crushing of medications can be organized for the hospital staff to update their knowledge about the topic.
3. Prescription monitoring can be done by clinical pharmacists in order to avoid the prescription of drugs that should not be crushed and helping in prescribing alternatives.
4. A more detailed study regarding the interaction of drugs with other drugs, food and the feeding tube itself can be conducted. The results of this study can be useful in the prescription of proper dosage forms and hence reducing the risk to patients.

BIBLIOGRAPHY

10. Bibliography

1. Clinical Guidelines (Nursing) : Enteral feeding and medication administration [Internet]. [cited 2019 Apr 8]. Available from: https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Enteral_feeding_and_medication_administration/

2. Demirkan K, Abbasoglu O. Assessment of drug administration via feeding tube and the knowledge of health-care professionals in a university hospital. 2016;71(2):164–8. Available from: http://dx.doi.org/10.1038/ejcn.2016.147

3. Gracia-Vásquez SL, González-Barranco P, Camacho-Mora IA, González-Santiago O, Vázquez-Rodríguez SA. Medications that should not be crushed. Med Univ [Internet]. 2017 Apr 1 [cited 2019 Apr 8];19(75):50–63. Available from: https://www.sciencedirect.com/science/article/pii/S1665579617300248

4. Shah HS, Chaturvedi K, Hamad M, Bates S, Hussain A, Morris K. New Insights on Solid-State Changes in the Levothyroxine Sodium Pentahydrate during Dehydration and its Relationship to Chemical Instability. AAPS PharmSciTech [Internet]. 2019 Jan 2 [cited 2019 Apr 9];20(1):39. Available from: http://link.springer.com/10.1208/s12249-018-1264-0

5. Boullata J, Brantley S, Corkins M, Guenter P, Krenitsky J, Lyman B, et al. Special Report Enteral Nutrition Practice Recommendations. 2009;33(2):122–67.

6. Sohrevardi SM, Jarahzadeh MH, Mirzaei E, Mirjalili M, Tafti AD, Heydari B. Medication Errors in Patients with Enteral Feeding Tubes in the Intensive Care Unit. J Res Pharm Pract [Internet]. 2017 [cited 2019 Apr 10];6(2):100–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28616433

7. Grissinger M. Preventing errors when drugs are given via enteral feeding tubes. P T [Internet]. 2013 Oct [cited 2019 Apr 8];38(10):575–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24391375

8. NEWT Guidelines - Admin Enteral Feeding Tubes [Internet]. [cited 2019 Apr 8]. Available from: http://www.newtguidelines.com/AdminEnteralFeedingTubes.html

9. Mafiana RN, Taqi A, Al-Zakwani I. Evaluation of nurses' knowledge of oral solid dosage forms that should not be crushed at a university hospital in Oman. J Pharm Heal Serv Res. 2014;5(1):49–53.

10. Stubbs J, Haw C, Dickens G. Dose form modification - A common but potentially hazardous practice. A literature review and study of medication administration to older psychiatric inpatients. Int Psychogeriatrics. 2008;20(3):616–27.

11. Seifert CF, Frye JL, Belknap DC, Anderson DC. A Nursing Survey to Determine the Characteristics of Medication Administration through Enteral Feeding Catheters. Clin Nurs Res [Internet]. 1995 Aug 25 [cited 2019 Apr 8];4(3):290–305. Available from: http://journals.sagepub.com/doi/10.1177/105477389500400306

12. Wright D. Medication administration in nursing homes. Nurs Stand [Internet]. 2002 Jul 3 [cited 2019 Apr 9];16(42):33–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12216309

13. Paradiso LM, Roughead EE, Gilbert AL, Cosh D, Nation RL, Barnes L, et al. Crushing or altering medications: what's happening in residential aged-care facilities? Australas J Ageing [Internet]. 2002 Sep 1 [cited 2019 Apr 9];21(3):123–7. Available from: http://doi.wiley.com/10.1111/j.1741-6612.2002.tb00432.x

14. Hanssens Y, Woods D, Alsulaiti A, Adheir F, Al-Meer N, Obaidan N. Improving Oral Medicine Administration in Patients with Swallowing Problems and Feeding Tubes. Ann Pharmacother [Internet]. 2006 Dec 29 [cited 2019 Apr 8];40(12):2142–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17132805

15. Mota MLS, Barbosa IV, Studart RMB, Melo EM, Lima FET, Mariano FA. Evaluation of Intensivist-Nurses' Knowledge Concerning Medication Administration Through Nasogastric and Enteral Tubes. Rev Lat Am Enfermagem. 2017;18(5):888–94.

16. Badri SDS. The role of clinical pharmacist to improve medication administration through enteral feeding tubes by nurses. 2012;757–64.

APPENDICES

APPENDIX 1: IEC Certificate

KASTURBA HOSPITAL
MANIPAL
(An associate Hospital of MAHE, Manipal)

Kasturba Medical College and Kasturba Hospital
Institutional Ethics Committee
(Registration No. ECR/146/Inst/KA/2013/RR-16)

Communication of the decision of the Institutional Ethics Committee

Wednesday 19th September 2018 **IEC : 568/2018**

Project title	:	Identifying and resolving potential problems associated with administration of drugs via nasogastric tube.
Principal Investigator	:	Miss. Priyanka. Pai.K
Guide/ Co Guide/ Co Investigators	:	Samriddhi Shree, Dr.Sreedharan, Dr. Surulivel Rajan M, Dr. Shivshankar K N
Name & Address of Institution	:	Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal, Department of Medicine, KMC, Manipal.
Status of review	:	New
Date of review	:	18.09.2018
Decision of the IEC	:	Approved for the study period from 18.09.2018 to 17.09.2019.

- The PI and all members of the project shall ensure compliance to current regulatory provisions (as per Schedule Y of Drugs and Cosmetics Act and ICH-GCP), Ethical Guidelines for Biomedical Research on Human Participants by ICMR, and the SOP of IEC including timely submission of Interim Annual Report and Final Closure Report
- Participant Information Sheet and a copy of signed Informed Consent shall be given to every research participant
- Inform IEC in case of any proposed amendments (change in protocol / procedure, site / Investigator etc)
- Inform IEC immediately in case of any Adverse Events and Serious Adverse Events.
- Members of IEC have the right to monitor any project with prior intimation.
- Ensure registration of this study at Clinical Trials Registry - India (CTRI) before the enrollment of the first participant (The registration number is to be forwarded to the IEC within 7 days of your successful registration).

Dr. Stanley Mathew
MEMBER SECRETARY - IEC

ETHICS COMMITTEE KASTURBA HOSPITAL, MANIPAL APPROVED

IEC Secretariat, Room No. 22, Ground Floor, Faculty Room Complex, Kasturba Medical College Premises,
Kasturba Medical College, Manipal - 576104, Karnataka, India. Phone : +91 - 0820 - 2933522,Fax : +91 - 0820 - 2571927. Email : iec.kmc@manipal.edu

(Yoga and Ayurveda services are excluded from the scope of NABH accreditation)

APPENDIX ll a: PIS ENGLISH

PARTICIPANT INFORMATION SHEET

Project title: Identifying and resolving potential problems associated with administration of drugs via nasogastric tube.
IEC No.: 568/2018
Sponsor Name:
Language: English

Principal Investigator: Priyanka. Pai. K
Designation: 2nd PharmD PB, Reg no:m170615004, Department of Pharmacy Practice
Hospital: Kasturba Medical College and Hospital
Mobile number: + 9972121551

Please read this form carefully. If you don't understand the language or any information in this document, please discuss with the study doctor. Your participation in this study is voluntary, and you can inquire about all details before giving your written consent to participate in this study.

1. Introduction to the research study:

You are invited to participate in this study because you are being administered medications through the nasogastric tube.

2. Purpose of the study:

- To assess the problems encountered when medications are administered by nasogastric tube (NGT) in a tertiary care hospital and develop a guide/chart for medication administration by the NGT.
- To conduct a questionnaire survey among nurse practitioners to assess their knowledge of drug administration through NGT.

3. Who can take part:

Patients of both gender who are admitted in Medicine ICU and are being administered medications via the nasogastric tube will be participating in this study. Pediatric patients and patients whose files are incomplete will not be participating in this study.

4. Information about the study (as a whole) :

Patients who are being administered medications via the nasogastric tube who are being admitted to the Medicine ICU of the Department of Medicine in Kasturba Hospital Manipal will be identified and studied. A prospective observational study on patients admitted under Medicine ICU's and receiving medications via the NGT will be identified. The data on medications [name of the drug (trade and generic) dosage form, strength, dose, and frequency] being administered before being crushed via NGT will be prospectively collected from the nursing case record and reviewed and the information would be deployed in preparing guide/chart/checklist.

5. What will happen to you (the individual participant) during the study: This is an observational study and we are only monitoring the drugs prescribed by the doctors and administered by the nurses.

6.Your (the individual participant) role/responsibility in the study: Since the study is an observational, non-interventional study and only the patients' files will be checked, there will be no role/responsibility for the individual participant in the study.

7. What are the risks?

As this is an observational non-interventional study, the risk to you will be minimal to none.

8. What are the potential benefits of participating in the study:

The results of the study will help to manage the problems associated with the administration of medications via NGT.

9. What are the alternative treatments available:

This study does not involve or influence any treatment; hence this section is not applicable.

10. Cost of participating in the study:

No additional costs or investigations incurred to the patients participating in the study.

11. Compensation for injury:

Since the study is an observational, non-interventional study and only the patients' files will be checked, this section is not applicable.

12. Confidentiality of information:

Information from the study will be kept confidential. The data will not be made available to another individual unless you specifically give permission in writing. Information and results from this study may be presented at meetings or published in journals without including your name and personal identifications. No reference will be made in oral or written reports which could link you to the study.

13. New information about the study:

Any new information available during the course of the study will be informed to you if it has relevance to your decision regarding continuing in the study. Results of your participation will be disclosed to you if you indicate your desire for it.

14. Voluntary participation:

Your participation in this study is voluntary; you may decline to participate at any time and you need not to give any reason for the same, and such withdrawal shall be without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non-participation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician.

If you withdraw from the study before data collection is completed, your data collected until you indicated withdrawal will be used in the study report. Sponsor or the investigator may stop the research or your participation in it at any time for some or other reason without your permission.

15. <u>Whom to contact in case of any questions:</u>

If you experience adverse effects as a result of participating in this study, you may contact the Principal Investigator Priyanka.Pai. K as detailed above.

If you have any questions about the informed consent process or your rights as a participant, you may contact the Member Secretary of the Kasturba Medical College and Kasturba Hospital - Institutional Ethics Committee at Room 22, Ground floor, KMC Faculty Rooms, adjacent to KMC Administrative Block, Kasturba Medical College, Manipal - 576104. Phone: 0820 29 33522. Timings: 9: 00 AM to 5: 00 PM.

If you have any questions about this form or any study related issue, you may also contact the following person.

Name: Mr. Prasanna Kumar Shetty, Associate Professor
Address: Department of Pharmacy Practice, MCOPS, Manipal 576104
Telephone No: +91- 9886725129

APPENDIX ll b: PIS KANNADA

ಅಧ್ಯಯನದ ಮಾಹಿತಿ ಪತ್ರ

ಅಧ್ಯಯನದ ಹೆಸರು: ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧಿಯನ್ನು ನೀಡುವಿಕೆಯಲ್ಲಿ ಒಳಗೊಂಡಿರುವ ಸಂಭಾವ್ಯ ತೊಂದರೆಗಳನ್ನು ಗುರುತಿಸುವಿಕೆ ಮತ್ತು ಪರಿಹರಿಸುವಿಕೆಯ ಅಧ್ಯಯನ.

ಅಧ್ಯಯನದ ಸಂಖ್ಯೆ:

ಪ್ರಾಯೋಜಕರು:

ಭಾಷೆ: ಕನ್ನಡ

ಮುಖ್ಯ ಸಂಶೋಧಕರು: ಪ್ರಿಯಾಂಕ ಪೈ. ಕೆ.

ಹುದ್ದೆ: 2ನೇ ಫಾರ್ಮಾ ಡಿ ಪಿ ಬಿ, ನೋಂದಣಿ ಸಂಖ್ಯೆ: ಎಂ 170615004, ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ್ ವಿಭಾಗ.

ಆಸ್ಪತ್ರೆ: ಕಸ್ತೂರ್ಬಾ ಮೆಡಿಕಲ್ ಕಾಲೇಜು ಮತ್ತು ಆಸ್ಪತ್ರೆ.

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 9972121551

ದಯವಿಟ್ಟು ಈ ಮಾಹಿತಿ ಪತ್ರವನ್ನು ಜಾಗರೂಕತೆಯಿಂದ ಓದಿರಿ. ನಿಮಗೆ ಇದರಲ್ಲಿನ ಭಾಷೆ ಅಥವಾ ಯಾವುದೇ ಮಾಹಿತಿಗಳು ಅರ್ಥವಾಗದೇ ಇದ್ದಲ್ಲಿ, ದಯವಿಟ್ಟು ಅಧ್ಯಯನಕಾರ ವೈದ್ಯರುಗಳ ಜೊತೆಯಲ್ಲಿ ಚರ್ಚಿಸಿರಿ. ಈ ಅಧ್ಯಯನಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿರುತ್ತದೆ. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ನೀಡುವ ಮೊದಲು ಅಧ್ಯಯನದ ವಿವರಗಳ ಬಗ್ಗೆ ವಿಚಾರಣೆ ಮಾಡಬಹುದು.

1.ಅಧ್ಯಯನದ ಪ್ರಸ್ತಾವನೆ:

ನಿಮ್ಮನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಆಹ್ವಾಹಿಸುತ್ತಿದ್ದೇವೆ ಏಕೆಂದರೆ, ನಿಮಗೆ ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧಿಗಳನ್ನು ನೀಡಲಾಗುತ್ತಿದೆ.

2. ಅಧ್ಯಯನದ ಉದ್ದೇಶ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ತೃತೀಯ ಮಟ್ಟದ ಆರೈಕೆಯ ಆಸ್ಪತ್ರೆಯಲ್ಲಿನ ಮಾರ್ಗದರ್ಶನದ ಅಭಿವೃದ್ಧಿ/ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧಿ ನೀಡುವಿಕೆಯಲ್ಲಿ ಎದುರಿಸುತ್ತಿರುವ ತೊಂದರೆಗಳನ್ನು ನಿರ್ಣಯಿಸಿ ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಶುಶ್ರೂಷೆ ನೀಡುವ ದಾದಿಯರಲ್ಲಿನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕವಾಗಿ ಔಷಧಿ ನೀಡುವಿಕೆಯಲ್ಲಿನ ಅವರ ತಿಳುವಳಿಕೆಯನ್ನು ಪ್ರಶ್ನಾವಳಿಯ ಸಮೀಕ್ಷೆಯ ಮೂಲಕ ನಿರ್ಣಯಿಸಲಾಗುತ್ತದೆ.

3. ಅಧ್ಯಯನದಲ್ಲಿ ಯಾರು ಭಾಗವಹಿಸುವರು:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ತೀವ್ರ ನಿಘಾ ಘಟಕದಲ್ಲಿ (ಐಸಿಯು) ದಾಖಲಾಗಿ ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧಿಯನ್ನು ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ ಎಲ್ಲಾ ಲಿಂಗದವರು ಭಾಗವಹಿಸುವರು.

ರೋಗಗ್ರಸ್ಥ ಮಕ್ಕಳು ಮತ್ತು ವೈದ್ಯಕೀಯ ವಿವರಗಳ ಕಡತಗಳು ಅಸಮರ್ಪಕವಾಗಿರುವವರು ಭಾಗವಹಿಸುವಂತಿಲ್ಲ.

4.ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಮಾಹಿತಿ (ಸಂಪೂರ್ಣ):

ಕಸ್ತೂರ್ಬಾ ಆಸ್ಪತ್ರೆಯಲ್ಲಿನ ಔಷಧ ವಿಭಾಗದ ತೀವ್ರ ನಿಘಾ ಘಟಕದಲ್ಲಿ (ಐಸಿಯು) ದಾಖಲಾಗಿ, ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧಿ ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ ರೋಗಿಗಳನ್ನು ಗುರುತಿಸಿ ಅಧ್ಯಯನ ನಡೆಸಲಾಗುತ್ತದೆ. ಇದು ಒಂದು ನಿರೀಕ್ಷಿತ ವೀಕ್ಷಣಾ ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ. ಇದರಲ್ಲಿ ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧ ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ ರೋಗಿಗಳ ವೈದ್ಯಕೀಯ ವಿವರಗಳನ್ನು, (ಔಷಧಿಯ ಹೆಸರು,{ವ್ಯಾಪಾರ ಮತ್ತು ಉತ್ಪಾದನೆ} ಔಷಧಿಯ ಪ್ರಮಾಣ, ಸಾಮರ್ಥ್ಯ, ನೀಡುವ ಪ್ರಮಾಣ ಮತ್ತು ಆವರ್ತನಗಳು) ಅಧ್ಯಯನ ನಡೆಸುವ ಮೊದಲು ಪಡೆಯಲಾಗುತ್ತದೆ.ವೈದ್ಯಕೀಯ ಪ್ರಕರಣದಲ್ಲಿ ನಿರೀಕ್ಷಿತವಾಗಿ ನಿಯೋಜಿತ ಕಾರ್ಯನಿರ್ವಹಣಾ ಮಾರ್ಗದರ್ಶಕರಿಂದ ಪಟ್ಟಿ, ಪರೀಕ್ಷವಿವರಪಟ್ಟಿಯ ಮಾಹಿತಿಗಳನ್ನು ಸಂಗ್ರಹಿಸಲಾಗುವುದು.

5. ಅಧ್ಯಯನದ ಸಂದರ್ಭದಲ್ಲಿ ನಿಮಗೆ ಏನಾಗಬಹುದು:

ಇದು ಒಂದು ವೀಕ್ಷಣಾ ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ. ಇದರಲ್ಲಿ ಕೇವಲ ವೈದ್ಯರ ಸೂಚನೆಯಂತೆ ದಾದಿಯರ ಔಷಧಿ ನೀಡುವಿಕೆಯ ಕಾರ್ಯನಿರ್ವಹಣೆಯನ್ನು ಗಮನಿಸಲಾಗುತ್ತದೆ.

6. ನಿಮ್ಮ(ಭಾಗೀದಾರರಿಗೆ ವೈಯಕ್ತಿಕವಾಗಿ) ಜವಾಬ್ದಾರಿ/ಪಾತ್ರ:

ಈತನಕ ಇದು ಒಂದು ವೀಕ್ಷಣಾ ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ. ಇದರಲ್ಲಿ ಯಾವುದೇ ಹಸ್ತಕ್ಷೇಪಗಳಿರುವುದಿಲ್ಲ ಮತ್ತು ಇದರಲ್ಲಿ ಕೇವಲ ರೋಗಿಯ ವೈದ್ಯಕೀಯ ಕಡತಗಳನ್ನು ಪರಿಶೀಲಿಸಲಾಗುವುದರಿಂದ ಭಾಗೀದಾರರಿಗೆ ವೈಯಕ್ತಿಕವಾಗಿ ಯಾವುದೇ ಪಾತ್ರ ಅಥವಾ ಜವಾಬ್ದಾರಿ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಇರುವುದಿಲ್ಲ.

7. ಅಪಾಯಗಳಾವುವು?.

ಇದು ಒಂದು ವೀಕ್ಷಣಾ ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ. ಇದರಲ್ಲಿ ಯಾವುದೇ ಹಸ್ತಕ್ಷೇಪಗಳಿರುವುದಿಲ್ಲ ಮತ್ತು ಅತ್ಯಂತ ಕನಿಷ್ಟ ಪ್ರಮಾಣದ ಅಪಾಯಗಳಿರುತ್ತದೆ.

8. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದರಿಂದ ಆಗಬಹುದಾದ ಸಂಭಾವ್ಯ ಪ್ರಯೋಜನಗಳು:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದರಿಂದ ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧ ನೀಡುವಿಕೆಯ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಒಳಗೊಂಡಿರುವ ತೊಂದರೆಗಳ ಬಗ್ಗೆ ತಿಳಿದುಕೊಳ್ಳಲು ಈ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶದಿಂದ ಸಹಾಯವಾಗುತ್ತದೆ.

9.ಯಾವ ಯಾವ ಪರ್ಯಾಯ ಚಿಕಿತ್ಸೆಗಳು ಲಭ್ಯ ಇವೆ?.

ಈ ಅಧ್ಯಯನವು ನಿಮ್ಮ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಯಾವುದೇ ಪ್ರಭಾವ ಬೀರುವುದಿಲ್ಲ ಆದುದರಿಂದ ಈ ವಿಭಾಗವು ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

10. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗಿಯಾಗುವುದರಿಂದ ತಗಲುವ ವೆಚ್ಚ:

ಈ ಅಧ್ಯಯನ ಅಥವಾ ಸಂಶೋಧನೆಗೆ ಹೆಚ್ಚುವರಿಯಾಗಿ ಹಣ ಪಾವತಿಸಬೇಕಾಗಿಲ್ಲ.

11. ಹಾನಿ/ತೊಂದರೆಗೆ ಪರಿಹಾರ.

ಈತನಕ ಇದು ಒಂದು ವೀಕ್ಷಣಾ ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ. ಇದರಲ್ಲಿ ಯಾವುದೇ ಹಸ್ತಕ್ಷೇಪಗಳಿರುವುದಿಲ್ಲ ಮತ್ತು ಇದರಲ್ಲಿ ಕೇವಲ ರೋಗಿಯ ವೈದ್ಯಕೀಯ ಕಡತಗಳನ್ನು ಪರಿಶೀಲಿಸಲಾಗುತ್ತದೆ. ಈ ವಿಭಾಗವು ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

12. ಮಾಹಿತಿಯ ಗೌಪ್ಯತೆ:

ಈ ಅಧ್ಯಯನದ ಮಾಹಿತಿಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುವುದು. ನಿಮ್ಮ ಲಿಖಿತ ಒಪ್ಪಿಗೆ ಇಲ್ಲದೇ ಈ ಅಧ್ಯಯನದ ವಿವರಗಳನ್ನು ಯಾವುದೇ ಅನ್ಯವ್ಯಕ್ತಿಗಳಿಗೆ ನೀಡಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶ ಹಾಗು ಮಾಹಿತಿಗಳನ್ನು ನಿಮ್ಮ ವೈಯಕ್ತಿಕ ಗುರುತು, ಹೆಸರು, ವಿಳಾಸಗಳಾವುದನ್ನೂ ತಿಳಿಯಪಡಿಸದೆ ಪ್ರಕಟಿಸಲೂಬಹುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ರೀತಿಯ ಮೌಖಿಕ ಮತ್ತು ಬರವಣಿಗೆಯ ವಿವರಣೆಗಳು ಆವಲಂಬನೆಯಾಗಿರುವುದಿಲ್ಲ.

13.ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಹೊಸ ಮಾಹಿತಿ.

ಈ ಅಧ್ಯಯನದ ಅಭ್ಯಾಸದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಹೊಸ ಮಾಹಿತಿಗಳು ಕಂಡುಬಂದಲ್ಲಿ ಅಭ್ಯಾಸ ಮುಂದುವರಿಸುವ ಬಗ್ಗೆ ನಿಮಗೆ ನಿರ್ಣಯಗಳನ್ನು ತಿಳಿಸಲಾಗುವುದು. ಈ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ಪಡೆಯಲು ನೀವು ಇಚ್ಛಿಸಿದಲ್ಲಿ, ಅದನ್ನು ನಿಮಗೆ ನೀಡಲಾಗುತ್ತದೆ.

14. ಐಚ್ಛಿಕ ಭಾಗವಹಿಸುವಿಕೆ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿದ್ದು, ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿಸಿದರೂ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮ ಸಮ್ಮತಿಯನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ಹಾಗು ಇದಕ್ಕೆ ಯಾವುದೇ ಕಾರಣ ನೀಡಬೇಕಾಗಿಲ್ಲ. ಇದಕ್ಕಾಗಿ ನಿಮಗೆ ಯಾವುದೇ ದಂಡವಿಲ್ಲ ಮತ್ತು ಸಿಗಬಹುದಾದ ಉಪಯೋಗ/ಲಾಭ/ನಷ್ಟವಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಮೊದಲು ಹೊರಬಂದರೆ ನಿಮಗೆ ಯಾವುದೇ ಚಿಕಿತ್ಸೆಗೆ ತೊಂದರೆಯಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಮುಂದಿನ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಯಾವ ಅಡ್ಡ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ ಅಥವಾ ನಿಮ್ಮ ವೈದ್ಯರೊಂದಿಗಿನ ಸಂಬಂಧಕ್ಕೆ ಯಾವುದೇ ತೊಂದರೆ ಇರುವುದಿಲ್ಲ.

ಅಧ್ಯಯನ ಪೂರ್ಣಗೊಳಿಸುವ ಮೊದಲು ನೀವು ಹಿಂದೆ ಸರಿದರೆ ನೀವು ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯುವ ಮೊದಲು ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಅಧ್ಯಯನದ ವರದಿಯಲ್ಲಿ ಉಪಯೋಗಿಸಲಾಗುವುದು. ಪ್ರಾಯೋಜಕರು ಅಥವಾ ಅಧ್ಯಯನಕಾರರು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅವರ ಅಧ್ಯಯನವನ್ನು ಅಥವಾ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಒಂದಲ್ಲ ಒಂದು ಕಾರಣಕ್ಕಾಗಿ ನಿಮ್ಮ ಅನುಮತಿ ಇಲ್ಲದೆಯೇ ನಿಲ್ಲಿಸಬಹುದು.

15.ಒಂದು ವೇಳೆ ಪ್ರಶ್ನೆಗಳೇನಾದರೂ ಇದ್ದಲ್ಲಿ, ಯಾರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ನಿಮಗೆ ಏನಾದರೂ ಪ್ರತಿಕೂಲ ಪೊಂದರೆಗಳು ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಕಂಡುಬಂದಲ್ಲಿ ಕೂಡಲೇ ಮುಖ್ಯ ಸಂಶೋಧನಾಕಾರ ಪ್ರಿಯಾಂಕ ಪೈ. ಕೆ. ಯವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯ ಒಪ್ಪಿಗೆ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನಕಾರರಲ್ಲಿ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುವ ಹಕ್ಕಿರುತ್ತದೆ. ಹಾಗಿದ್ದಲ್ಲಿ,ನಿಮಗೆ ಸದಸ್ಯ ಕಾರ್ಯದರ್ಶಿಗಳು, ಕಸ್ತೂರ್ಬಾ ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ಮಣಿಪಾಲದ ನೈತಿಕ ಸಮಿತಿ ಸಂಸ್ಥೆಯ ಕೊಠಡಿ ಸಂಖ್ಯೆ 22, ಬೆಲಮಹದು, ಕೆ.ಎಮ್.ಸಿ. ಸಿಬ್ಬಂದಿಗಳ ಕೊಠಡಿ, ಕೆ.ಎಮ್.ಸಿ ಆಡಳಿತ ವಿಭಾಗ ಕಛೇರಿಯ ಪಕ್ಕ, ಕಸ್ತೂರ್ಬಾ ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ಮಣಿಪಾಲ-576 104 ಇವರು ವಿವರಗಳನ್ನು ನೀಡುತ್ತಾರೆ.

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 0820 2933522 ಸಮಯ: 9:00ಬೆಳಗ್ಗೆ. 5:00ಸಂಜೆ.

ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಯಾವುದಾದರೂ ಪ್ರಶ್ನೆ ಅಥವಾ ಸಂಬಂದಿಸಿದ ವಿಷಯಗಳಿದ್ದಲ್ಲಿ, ಈ ಕೆಳಗೆ ತಿಳಿಸಿದ ವ್ಯಕ್ತಿಗಳನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಹೆಸರು: ಶ್ರೀ ಪ್ರಸನ್ನ ಕುಮಾರ್ ಶೆಟ್ಟಿ.
ಅಸಿಸ್ಟಂಟ್ ಪ್ರೊಫೆಸರ್,
ವಿಳಾಸ: ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ್ ವಿಭಾಗ. ಎಂ ಸಿ ಓ ಪಿ ಎಸ್,ಮಣಿಪಾಲ.
ದೂರವಾಣಿ ಸಂಖ್ಯೆ: +91 9886725129

APPENDIX ll c: PIS Nurses

Project title: Identifying and resolving potential problems associated with administration of drugs via nasogastric tube.

IEC No.: 568/2018
Sponsor Name:
Language: English

Principal Investigator: Priyanka. Pai. K
Designation: 2nd PharmD PB, Reg.No. 170615004, Department of Pharmacy Practice
Hospital: Kasturba medical college and hospital.
Mobile number: +91 9972121551

Please read this form carefully. If you don't understand the language or any information in this document, please discuss with the study doctor. Your participation in this study is voluntary, and you can inquire about all the details before giving your written consent to participate in this study.

Introduction to the research study: You are invited to this study to assess your knowledge of drug administration through NGT via a questionnaire.

1. **Purpose of the study:**
   - To assess the problems encountered when medications are administered by nasogastric tube (NGT) in a tertiary care hospital and develop a guide/chart for medication administration by the NGT.
   - To conduct a questionnaire survey among nurse practitioners to assess their knowledge of drug administration through NGT.

3. **Who can take part:**
Nurses working in the Medicine ICU units of Kasturba Medical Hospital

4. **Information about the study:**
A prospective observational study on patients admitted under Medicine ICU's and receiving medications via the NGT will be identified. The data on medications [name of the drug (trade and generic) dosage form, strength, dose, and frequency] being administered before being crushed via NGT will be prospectively collected from the nursing case record and reviewed and the information would be deployed in preparing guide/chart/checklist. An interviewer-administered questionnaire will be used to assess the knowledge of nurse practitioners.

5. **What will happen to you during the study:**
You will be asked a set of questions from a questionnaire to check about your knowledge of drug administration through the nasogastric tube. Your answers will be recorded on the questionnaire sheet for further assessment.

6. **Your role/responsibility in the study:**
Provide accurate information whenever asked.

7. **What are the risks**?
As this is an observational non-interventional study, the risk to you will be minimal to none.

8. **What are the potential benefits of participating in the study** :
The results of the study will help to manage the problems associated with the administration of medications via NGT

9. **What are the alternative treatments available**:
Since this is an observational, non-interventional study, this section is not applicable.

10. **Cost of participating in the study**:

No additional costs for participating in the study.

11. **Compensation for injury:**
Since this is an observational, non-interventional study, this section is not applicable.

12. **Confidentiality of information**:

Information from the study will be kept confidential. The data will not be made available to another individual unless you specifically give permission in writing. Information and results from this study may be presented at meetings or published in journals without including your name and personal identifications. No reference will be made in oral or written reports which could link you to the study.

13. **New information about the study:**

Any new information available during the study will be informed to you if it has relevance to your decision regarding continuing in the study. Results of your participation will be disclosed to you if you indicate your desire for it.

14. **Voluntary participation**:

Your participation in this study is voluntary; you may decline to participate at any time and you need not to give any reason for the same, and such withdrawal shall be without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your nonparticipation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician.

If you withdraw from the study before data collection is completed, your data collected until you indicated withdrawal will be used in the study report. The investigator may stop the research or your participation in it at any time for some or other reason without your permission.

15. **Whom to contact in case of any questions:**
If you experience any adverse effects as a result of participating in this study, you may contact the Principal Investigator Priyanka.Pai.K If you have any questions about the informed consent process or your rights as a participant, you may contact the Member Secretary of the Kasturba Medical College and Kasturba Hospital - Institutional Ethics Committee at Room 22, Ground floor, KMC Faculty Rooms, adjacent to KMC Administrative Block, Kasturba Medical College, Manipal - 576104. Phone: 0820 29 33522. Timings: 9: 00 AM to 5: 00 PM.
If you have any questions about this form or any study related issue, you may also contact the following person.
Name: Mr. Prasanna Kumar Shetty, Associate Professor

Address: Department of Pharmacy Practice, MCOPS , Manipal 576104
Mobile No. +91 98867251

APPENDIX lll a: IC ENGLISH

INFORMED CONSENT FORM

Project title: Identifying and resolving potential problems associated with administration of drugs via nasogastric tube.

I confirm I have read the Participant Information Sheet for the above study and its contents were explained and I have had the opportunity to ask questions and received satisfactory answers.

I understand that my participation in the study is voluntary and that I have the right to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I agree to take part in the above study. I confirm that I have received a copy of the Participant Information Sheet along with this signed and dated informed consent form.

Name of the Research Participant :

Age of the Research Participant :

Address of the Research Participant :

Occupation :

Annual Income of the Participant :

Name & address of the nominee(s) and his relation to the Participant :

_____

_____ _____
Signature of the research subject Date

_____ _____
Name & Signature of the witness Date

_____ _____
Name & Signature of the person explaining the consent Date

APPENDIX lll b: IC KANNADA

ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ಪತ್ರ

ಅಧ್ಯಯನದ ಹೆಸರು: ನಾಸೋಗ್ಯಾಸ್ಟ್ರಿಕ್ ಕೊಳವೆಯ ಮೂಲಕ ಔಷಧಿಯನ್ನು ನೀಡುವಿಕೆಯಲ್ಲಿ ಒಳಗೊಂಡಿರುವ ಸಂಭಾವ್ಯ ತೊಂದರೆಗಳನ್ನು ಗುರುತಿಸುವಿಕೆ ಮತ್ತು ಪರಿಹರಿಸುವಿಕೆಯ ಅಧ್ಯಯನ.

ನಾನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗೀದಾರರ ಮಾಹಿತಿ ಪತ್ರವನ್ನು ಓದಿ ತಿಳಿದುಕೊಂಡಿರುತ್ತೇನೆ. ಮತ್ತು ಅದರಲ್ಲಿನ ಮಾಹಿತಿಗಳನ್ನು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ. ನನಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶ ನೀಡಲಾಗಿದ್ದು, ಅವುಗಳಿಗೆ ಸಮಾಧಾನಕರವಾದ ಉತ್ತರಗಳು ಲಭಿಸಿವೆ ಎಂದು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಈ ಮಾಹಿತಿ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ನನಗೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ, ಯಾವುದೇ ಕಾರಣವಿಲ್ಲದೆ ವೈಯಕ್ತಿಕವಾಗಿ ಭಾಗವಹಿಸುವಿಕೆಯಿಂದ ಹಿಂದೆ ಸರಿಯುವ ಹಕ್ಕಿದೆ. ಈ ನಿರ್ಣಯವು ಮುಂದಿನ ವೈದ್ಯಕೀಯ ತಪಾಸಣೆಗೆ, ಕಾನೂನು ಹಕ್ಕಿಗೆ ಯಾವುದೇ ತೊಂದರೆಯಾಗುವುದಿಲ್ಲವೆಂದು ತಿಳಿದಿರುತ್ತೇನೆ.

ನಾನು ಮೇಲೆ ತಿಳಿಸಿದ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಂಡಿದ್ದು ಹಾಗೂ ನಾನು ಸಹಿ ಮಾಡಿದ ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ಪ್ರತಿಯನ್ನು ಈ ಕೆಳಗಿನ ದಿನಾಂಕದಂದು ಸ್ವೀಕರಿಸಿರುವೆನೆಂದು ಖಚಿತಪಡಿಸಿಕೊಂಡಿದ್ದೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು:

ಭಾಗವಹಿಸುವವರ ವಯಸ್ಸು:

ಭಾಗವಹಿಸುವವರ ವಿಳಾಸ:

ಉದ್ಯೋಗ:

ಭಾಗವಹಿಸುವವರ ವಾರ್ಷಿಕ ಆದಾಯ:

ನೊಮಿನಿಯ(ರ) ಹೆಸರು ಮತ್ತು ವಿಳಾಸ ಮತ್ತು ಭಾಗವಹಿಸುವವರ ಜೊತೆಗೆ ಇರುವ ಸಂಬಂಧ :

_____ _____

ಭಾಗವಹಿಸುವವರ ಸಹಿ ದಿನಾಂಕ

_____ _____

ಸಾಕ್ಷಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ ದಿನಾಂಕ

_____ _____

ಒಪ್ಪಿಗೆ ವಿವರಿಸುವ ವ್ಯಕ್ತಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ ದಿನಾಂಕ

APPENDIX IV: DATA COLLECTION FORM

DATA COLLECTION FORM

HOSP NO: IP NO: AGE: SEX: M/F WEIGHT:	DATE OF ADMISSION: DATE OF DISCHARGE: DATE OF INTUBATION: NO OF DAYS INTUBATED:

COMPLAINTS ON ADMISSION:

MEDICAL HISTORY:
MEDICATION HISTORY:
SOCIAL HISTORY:
PREVIOUS ALLERGIESS:

REASON FOR INTUBATION:

FINAL DIAGNOSIS:

DRUG CHART

DRUG	GENERIC NAME	FREQUENCY	DOSAGE FORM	OBSERVATIONS	REMARKS

MEDIUM OF ADMINISTRATION:

APPENDIX V: QUESTIONNAIRE

Questionnaire

UNIT: ……. SL NO…….

1. Is it appropriate to crush sustained release/controlled-release tablets before administration?
   A) Yes B) No
2. Are enteric coated tablets supposed to be crushed before administration?
   A) Yes B) No
3. Do you asses the appropriateness of the dosage form of drugs before administering it to the patients through the NGT?
   A) Yes B) No
4. Are you aware of the fact that certain tablets/capsules should not be crushed/opened? If yes, please name some products
   A) Yes B) No

   …….
5. Do you administer all the medications at once through the NGT?
   A) Yes B) No
6. Do you wash the pipe between administrations of different drugs?
   A) Yes B) No
7. Are you aware of the problems associated with concurrent administration of drugs through the NGT?
   A) Yes B) No
8. How do you crush the medication before administration through NGT?

   ……..
9. Do you prepare a suspension of the medicine before administering it through the tube? If yes, what medium is used to prepare the suspension?
   A) Yes B) No

   ……..
10. Do you take help from the doctor or pharmacist regarding administration of medications through the NGT?
    A) Yes B) No
11. Would you like to attend CE programs on administration of drugs through the NGT?
    A) Yes B) No

Identifying and resolving problems associated with administration of medications through the NGT

ORIGINALITY REPORT

11%	7%	6%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.newtguidelines.com Internet Source	3%
2	Mafiana, Rose Ngozi, Aqeela Taqi, and Ibrahim Al-Zakwani. "Evaluation of nurses' knowledge of oral solid dosage forms that should not be crushed at a university hospital in Oman : Nurses' knowledge of oral solid dosage forms", Journal of Pharmaceutical Health Services Research, 2014. Publication	2%
3	S.L. Gracia-Vásquez, P. González-Barranco, I.A. Camacho-Mora, O. González-Santiago, S.A. Vázquez-Rodríguez. "Medications that should not be crushed", Medicina Universitaria, 2017 Publication	1%
4	www.rch.org.au Internet Source	1%
5	www.healthmed.ba Internet Source	<1%