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Original Article

A prospective observational study on evaluation of medication safety on anaesthesia in Ordibehesht Hospital, Shiraz, Iran

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ABSTRACT

The goal of the study is to A Prospective Observational Study on Evaluation of Medication Safety on Anesthesia in Ordibehesht Hospital, Shiraz, Iran. Study was conducted for a period of 6 months from October 2020_march 2021. The results of this study showed male patients were listed more (n= 60(60%)) than the female patient (n=40(40%)), majority number of patients were in 19-55 years age group, general surgical was the common procedure (n=34, (34%)), The majority of reported incidents occurred among (ASA II risk, n=57(57%)) patients. general anesthesia was the major rout administered for most of the patient. In this study we found that, neuromuscular blocker (13.36%) and analgesics (12.9%) drugs were mostly used with anesthesia agents during surgery. Morphine (44.5%) was the major analgesics used in most of the surgery. we also founded that there is some drug-drug interaction between anesthetic drugs with each other and with other drugs used during of surgery. we founded that in 100 patients, interaction between isoflurane and fentanyl was the mostly drug-drug interaction(n=65(65%)). We also founded that there were many factors which contributing in medication error of anesthesia; most anesthesiologists experienced at least one drug error. The commonest error was the misidentification of ampoule/vial, (55%, n = 22) Most errors were of minor consequence, however, serious morbidity and mortality resulted from clearly preventable events. These results support the development of improved standards for drug labels.

Keywords: Anesthesia, Medication safety, ASA risk, Drug interactions.

Introduction

Background

Ensuring patient safety has become a central goal in modern healthcare systems, and a key component of this effort is the safe administration of medications. Medication safety is especially critical in the field of anesthesia, where a small error in drug selection, dosage, or route of administration can result in immediate and severe consequences. Anesthesia is a unique domain within clinical medicine, characterized by rapid decision-making, simultaneous management of multiple physiological parameters, and the use of high-risk medications. The administration of anesthetic agents is often performed under pressure and without verification systems common in other settings, increasing the vulnerability to errors (Merry & Anderson, 2011). Anesthetic drugs are typically administered during the perioperative period, which includes preoperative preparation, intraoperative management, and postoperative recovery. These drugs include induction agents such as propofol and thiopentone, maintenance agents like sevoflurane or isoflurane, neuromuscular blockers such as vecuronium or rocuronium, opioid analgesics, antiemetics, and various adjuvants. Most of these drugs have a narrow therapeutic index, meaning that there is a small margin between therapeutic and toxic doses (Cooper et al., 2012). Therefore, any deviation from the intended dose or incorrect drug administration can quickly become catastrophic. In the operating theatre, anesthesiologists or nurse anesthetists often draw up, label, and administer medications themselves, without a second person checking the accuracy of the drug or dose. This self-contained process is efficient but lacks the double-checking safety mechanisms often present in other parts of the hospital. Furthermore, anesthetic practice often requires multitasking in an environment with frequent interruptions, distractions, time constraints, and high cognitive load—all contributing to the risk of human error (Reason, 2000).

Nature of medication errors

in Anesthesia Medication errors are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the healthcare professional, patient, or consumer (National Coordinating Council for Medication Error Reporting and Prevention, 2021). In anesthesia, these errors can occur at any stage: prescribing, preparation, labelling, administration, or documentation. The most common types of medication errors in anesthesia include: • Wrong drug: Administering a different drug than intended due to similar names or packaging

• Wrong dose: Giving more or less than the required dose.

• Wrong route: For example, injecting an intravenous drug intrathecally.

• Omission: Forgetting to administer a required medication.

• Duplication: Administering a drug that has already been given. Such errors are frequently associated with similar-looking ampoules, illegible handwriting, poor labelling, and fatigue (Wheeler et al., 2008). While some errors are intercepted before causing harm (near-misses), others result in adverse drug events (ADEs) that may cause hypotension, allergic reactions, prolonged sedation, or even death.

Rationale of the study

Although anesthesia is generally considered safe due to improvements in technology, training, and protocols, medication errors remain a persistent and underreported problem. Studies suggest that a significant proportion of medication errors in anesthesia are preventable. In one prospective observational study involving over 2700 anesthetic procedures, Nanji et al. (2016) reported a medication error or adverse drug event in 5.3% of administrations. Alarmingly, nearly 80% of these were deemed preventable.

A major reason for the underreporting of errors is the fear of blame and legal consequences. The traditional "blame culture" in healthcare discourages staff from reporting incidents, which in turn limits institutional learning and system improvement. A shift towards a "just culture" that focuses on learning and system redesign is essential to reduce future errors (Leape, 1994).

This study is vital to understand how often medication errors occur in anesthesia practice, what types are most common, and what systemic or human factors contribute to their occurrence. By evaluating medication safety practices in real-world clinical environments, this research will contribute meaningful data to improve safety protocols and reduce harm to patients undergoing anesthesia. This study done with the objective of analysis of medication errors in a teaching hospital with an aim towards process improvement is thus justified.

Materials and Methods

In this prospective observational study, anesthesia-trained study staff (anesthesiologists/nurse anesthetists) observed randomly selected operations at a 100 patient in medical center over six months.

the study was conducted in the department of surgery Ordibehesht Hospital.

Ordibehesht Hospital has provided Shiraz with outstanding medical care. Located on Chamran Blvd in a green and leafy area of Shiraz, Iran. Ordibehesht Hospital serves the Greater Shiraz Community and beyond. We provide some of the region's best care, including a variety of quality clinical and surgical services.

The first step after selection of topic in the study was to design a data collection form. the patient data collection was used to collect all the details like inpatient number, age, sex, social history, anesthetic plan, procedure, ASA risk, laboratory data, diagnosis, therapeutic management.

The second step in the study was OT chart(annexure2) analysis it was used to study various parameters prescription legibility and completeness, contraindication, drug interactions, anesthesia plan, ASA risk, elective or emergency surgery and procedure.

The prescription guidelines, Micromedex, Interaction Checker, Drug Interaction Database and Stockley's Drug Interaction Book 8 Edition, Miller's Anesthesia, Ot Chart and Case Charts.

The drug interaction in prescription was collected and then compare with guidelines.

When the analysis of prescription was completed then all data enter to the appropriate software and the results were gained.

Other part of study was providing Questionnaire assessment consisting of 17 questions related to the causes of medication error and document filled by the physicians and nurses in OT and surgery ward for investigating the factors contributing to medication errors. responses entered in the excel sheet, analyzed and given rank according to the percentage from A to F (A had highest level of importance and F had lowest level of importance)

Results and Discussion

the study was conducted in the department of surgery Ordibehesht Hospital. Out of 100 patient included for the study , (n=2,2%)patient had an age 0-10 years And out of this age group (n=1,1%) was female and (n=1,1%) was male , (n=8,8%) patient had An age 11-20 years and out of this age group (n=5,5%) was female and (n=3,3%) was male , (n=22,22%)patient had an age 21-30 years and out of this age group (n=10,10%) was female And (n=12,12%) was male,(n=12,12%)patient had an age 31-40years out of this age group(n=3,3%)was female and (n=9,9%)was male,(n=16,16%) patient had an age 41-50years and out of this age group(n=8,8%)was female and(n=8,8%)was male,(n=23,23%)patient had an age 51-60years and out of this age group(n=6,6%)was female and (n=17,17%) was male, and (n=17,17%)patient had an age>60years and out of this age group(n=7,7%)was female and (n=10,10%)was male.

Out of 100 patient included for the study ,28(28%)patient had a surgery in ASA risk 1 And out of this group 16(16%) was elective surgery and 12(12%)was emergency surgery , 57(57%)patient had a surgery in ASA risk2 and out of this group 38(38%) was

elective surgery and19(19%) was emergency surgery,11(11%)patient had a surgery in ASA risk 3 and out of this group 6(6%) was elective surgery and 5(5%) was emergency surgery,4(4%)patient had a surgery in ASA risk 4 and out of this group 0(0%)was elective surgery and 4(4%)was emergency surgery.

Out of 61 drug interaction included for the study (n=42,68.8%)are in MAJOR group of severity and out of this group(n=23,54.8%) was seen in male and(n=19,45.2%)was seen in female,(n=17,27.8%) are in MODERATE group of severity and out of this group(n=10,58.8%) was seen in male and(n=7,41.1%)was seen in female,(n=2,3.2%) are in MINOR group of severity and out of this group 2 was seen in male and 0(0%) was seen in female.

Table1. Most Commonly class of drugs used in surgery with a naesthetic

DIFFERENT CLASS OF DRUGS USED IN SURGERY WITH ANAESTHETICS	TOTAL NUMBER (%)
ANTIBIOTIC	45(6.8%)
ANAESTHETICS	313(49.9%)
ADRENERGIC AGONIST	7(1.10%)
ANALGESIC	81(12.9%)
ANTICHLONERGIC	46(7.33%)
ANTIEMETIC	49(7.75%)
ANTIDIABETIC	1(0.1%)
CARDIOVASCULAR AGENT	1(0.1%)
NEUROMUSCULAR BLOCKER	82(13.36%)
UTERINE STIMULANT	2(0.31%)

Table 1 shows NEUROMUSCULAR BLOCKERS 82(13.36%) and ANALGESIC 81(12.6%) and ANTIBIOTIC 55(8.7%) were most commonly used class of drug with anesthetics agents during surgery.

In this study we found that, neuromuscular blocker (13.36%) and analgesics (12.9%) drugs were mostly used with anesthesia agents during surgery. Morphine (44.5%) was the major analgesics used in most of the surgery with anesthetics agents, also Atracurium (48.3%) was commonly used more than depolarizing neuromuscular blockers, as suxamethonium (17.2%) compare to other neuromuscular blockers.

This result in some aspects is same as results that found with S. C. Hodges *et al*, in their result morphine (45%) was the most analgesic used during the anesthesia and surgery but in their result, Supplies of suxamethonium were (54%) compared to nondepolarising neuromuscular blocking drugs, as ATRACURIUM (15%), which is completely different with our result.

Categorization of drug interactions based on mechanism are shown in table 5, the study shows that drug interaction had a greater number of pharmaco dynamics interaction (94.8%) than compared to pharmacokinetics interactions (5.1%) also table shows a greater number of major interaction (68.8%) as compared to moderate (27.8%) and minor interaction (3.2%). Table 2

Table 2. Severity and mechanism of drug interaction

DRUG-DRUG INTERACTION	TYPE	TOTAL NUMBER	FEMALE	MALE	(%)
SEVERITY	MAJOR	42	19 (45.2%)	23 (54.8%)	68.8%
	MODERATE	17	7 (41.1%)	10 (58.8%)	27.8%
	MINOR	2	0	2	3.2%
	TOTAL	61	26 (46%)	33 (54%)	100%
PHARMACOKINETIC INTERACTION	ABSORPTION	-			-
	METABOLISM	3			5.1%
	EXTRACTION	-			-
	DISTRIBUTION	-			-
	TOTAL	3(5.1%)			5.1%
PHARMACODYNAMIC INTERACTION	SYNERGISM	48			76.9%
	ANTAGONISM	10			17.9%
	NEUTRALIZATION	-			-
	TOTAL	58(94.8%)			94.8%
TOTAL	-	61			

Out of 313 number of anaesthetics agent used, fentanyl (iv anaesthetic agent) is the most commonly anaesthetic agent used 76(24.2%), and the second agent is isoflurane (inhalation anaesthetic agent) with 62(19.8%) percentage. ***TABLE3***

Table3. Most anaesthetic agent used

MOST NAESTHETIC AGENTS	%	TOTAL NUMBER
FENTANYL	24.2%	76
ISOFLURANE	19.8%	62
PROPOFOL	17.2%	54

MIDAZOLAM	**14.3%**	**45**
LIGNOCAIN	**10.2%**	**32**
SENSORCAIN	**4.7%**	**15**
SEVOFLURANE	**4.1%**	**13**
THIOPENTAL	**3.1%**	**10**
KETAMINE	**1.9%**	**6**
TOTAL	**100%**	**313**

Table4: Anaesthetic plan

PLAN	NUMBER	MALE	FEMALE	%
GENERAL	69	36	33	69%
SPINAL	12	9	3	12%
GENERAL/SPINAL	15	12	3	15%
EPIDURAL	-	-	-	-
GENERAL/EPIDURAL	3	3	-	3%
GENERAL/SPINAL/EPIDURAL	1	-	1	1%
TOTAL	100	60	40	100 %

Intraoperative vital sign observations were not intelligible in21 cases (Table 4). Together with those notes in which no record was made, this means that in 100 cases, no useful record of vital signs pertaining to the anesthetic were available. A further 18 records were designated as incomplete, thus resulting in a total of 100 records in which the vital signs would have been of minimal use as a record of events.

Table 5. Diagnosis and procedure

DIAGNOSIS	DISORDER	PLAN	PATIENT GENDER		TOTAL
			MALE	FEMALE	
GIT	ACUTE APPENDICITIS	LAPROSCOPY	1	7	8
	PAIN IN ABDOMEN	LAPROSCOPY/LAPRATOMY	1	4	5
	GALL STONE	CHOLECYTOCTOMY	1	5	6
	EPISTAXIS	ENDOSCOPY	1	4	5
2.METABOLIC	DM/HTN	STSG	4	4	8
	HERNIA	HERNIOPLASTY	3	4	7
	OSTEOMENINGITIS	SEMESTUCTOMY	1	1	2
INFECTION	AXILARY BIOPSY	LM BIOPSY	1	1	2
	SEPSIS	URS	1	1	2
	UTI	LAPROSCOPY	1	4	5
	INTESTINAL INFECTION	LAPROSCOPY	3	6	9
RENAL	ANAL ABSSEY	ISD	1	3	4
CANCER	BREAST/STOMACH	MASTOPLASTY	2	7	9
ACCIDENT			12	6	18
OTHER			4	6	10
TOTAL			37	63	100

TABLE6: QUESTIONAIRRE

The questioner fills in Iran which is show the factors effecting in medication error.

A) DEMOGRAPHIC

QUESTION	MOST FREQUENCY ANSWER	NUMBER (%)
1-how many years have u practiced anesthesia?	**0-5yrs**	**17(42.5 %)**
2-where do u practice anesthesia?	University teaching center	**14(35%)**
3-have you undergone any anesthesia administration training?	**Yes**	**32(80%)**
4-what percent of your time is spent administering anesthesia?	**>75**	**14(35%)**

B) PREVALENCE OF DRUG ERRORS IN ANESTHETIC PRACTICE:

QUESTION	MOST FREQUENCY ANSWER	NUMBER (%)
1-in the course of administering anesthesia, have you ever given the wrong drug to a patient?	**yes**	**19(47.5%)**
2-name of the drugs involved	Lidocaine instead of midazola, **-**	**4(20%)**
3-write mostly factors contribute to drug error	**Misidentification of ampoule/vial -did not readlable**	**20(50 %)**
4-what was effect of each error on outcome?	**No clinical drug significance**	**32(80 %)**

C) FEATURES OF DRUG LABELING AND PACKAGING

QUESTION	MOSTL FREQUENCY ANSWER	NUMBER (%)
1-how often do you read the drug name on label?	always	**19(47.5%)**
2-what the single most important feature of the label that helps you identify a drug used in the OR?	**Read label**	**33(82.5%)**
3-what characteristics of a drug direct you **to pick** that containers out from your drug cart when drawing up anesthetic drug?	**Drug label**	**32(80%)**
4-are you aware of the availability of color-coded CSA standardized labels for anesthetic drug syringes?	**yes**	**24(60%)**
5-do you use these color –coded self-adhesive labels?	**yes**	**14(35%)**
6did -color-coded self-adhesive labels decrease the incidence of drug error in anesthesia?	**Strongly agree**	**28(70%)**

D)REPORTING OF DRUG ERROR

QUESTION	MOST FREQUENCY ANSWER	NUMBER (%)
1-Did you report any drug error?	**yes**	**29(72.5%)**
2-to whom or where did you report the error?	**Chief medical surgery and HOD**	**29(72.5%)**
3-if you did not report the error, why?	**Error was inconsequential**	**5(25%)**
4-was the patient notified of the drug error?	**no**	**20(50%)**
5-would you have reported a single reporting agency?	**yes**	**33(82.5%)**
6-what steps were taken to prevent such a drug error?	**Labeling properly**	**32(80%)**

Table 7. Comperation Result Of Questioner In Iran

		IRAN
DEMOGRAPHIC	1.years of practice	0-5yrs
	2.place of practice	university
	3.undergoing training	Yes
	4.%of spending time	50-75%
PREVALENCE OF ERROR PRACTICE	1.giving wrong drug	Rarely
	2.most common drug error name	Lidocaine instead of midazolam
	3.factor contribute	Misunderstand and vial and ampoule
	4.effect of drug error	No clinical significance
EFFECT OF LABELING AND PACKAGING	1.read drug label	always
	2.important characteristic for identifying of drug	Read label
	3.most important characteristic for reducing drug error	Read drug label
REPORT OF ERROR	1.report of error	yes
	2.to where/who report	Chief of surgery
	3 if not report, why?	Error was inconsequential

In this study we were founded that there is some drug-drug interaction between anesthetic drugs with each other and with other drugs used during of surgery. We founded that in 100 patients, interaction between isoflurane and fentanyl was the mostly drug-drug interaction(n=65(65%)), which caused additive CNC depression, respiratory depression and hypotension, so patient must be monitored carefully, and dose of one or both of drug must be adjusted.

This result was same with the result which founded by STOCKLY'S drug interaction edited by Karen baxter, concomitant use of fentanyl, which is a CNS depressant, with another CNS depressant may result in respiratory depression, hypotension, so carefully monitored the patient received concomitant fentanyl and other CNS depressant and adjust dosage of one or both agents (Baxter, K. et.al (2010)

In our study the second mostly drug-drug interaction founded was between morphine and fentanyl (n=56(56%), which caused additive CNS depression and respiratory depression, so patient must be monitored carefully or adjusted dose of one or both of drug.

This result was same with result founded by Stockly's drug interaction, the combination of fentanyl and morphine (anesthetic agent with opioid) result on more pronounced respiratory depression than morphine alone. (Baxter, K. et.al (2010)

Other part of our study was investigated about factor contributing in medication error in anesthesia table (14) shows results of opinion of 40 number of anesthesiologist physicians and technicians. Most responders had practiced anesthesia for 0-5 yr. (42.5%) and were trained as specialists in anesthesia (80%). Respondents usually practiced in university-teaching center (35%) and spent greater than 75% of their professional time providing clinical care (35%).

This result in some aspects had similarly with study of Beverley A. Orser *et al*, their demographic profile shows that responders had practiced anesthesia mostly for 5 - 10 yr. and were trained as specialists in anesthesia (FRCPC or equivalent certification). Respondents usually practiced in university-affiliated teaching hospitals and spent > 75% of their professional time for administering anesthetics. (Orser, B. A. et.al (2001).

In the second part of our questionnaire, we asked about prevalence of drug error in the course of administering anesthesia. 47.5% (n= 19) of responders reported (yes) while 20% (n = 8) reported (Almost)

And 32.5% (n=13) reported that they had (never) experienced an error. The misidentification of ampoule/vial, was the most common cause of error (55%, n = 22), failure to read the label (50%, n = 20), and syringe swap (42.5%, n = 17). The majority of the adverse events were either of minor morbidity, (32%, n =13), or no clinical importance, (80%, n =32) and (10%, n=4) were in major morbidity.

This result was similar to result of Orser *et al*, in their study 61.7% (n = 424) of responders reported actual errors while 9.6% (n = 66) reported "near misses". A "near miss" is an event in which the drug was not actually administered. Ninety-five of the respondents (13.98%) described both an actual error and "near miss", while a Similar number 103 (14.9%) reported that they had never experienced an error. The misidentification of a syringe or "syringe swap" was the most common cause of error (70.4%, n = 413). Other contributing factors included a failure to read the label (62.9%, n = 367), and misidentification of the drug ampoule or vial (46.8%, n = 274). The majority of the adverse events were either of minor consequence, (35.4%, n = 368), or no clinical importance, (57.5%, n = 597). Fifteen drug errors (1.4%) resulted in major morbidity (including cardiac arrest, stroke or permanent injury). (Orser, B. A. et.al (2001).

In third part, when we asked, "In your estimation, how often do you actually READ the drug name on the label if you are working in your usual workplace? Most anesthesiologists reported (always) 47.5%, (mostly) 25%, (sometime), 25% and (never) 2.5%. Many responders identified color as the most important feature used to identify drugs (57.5%, n=23), Drug name or label (80%, n=32) and Shape/size of container (40%, n=16). When asked if they believed these labels decrease the incidence of drug errors, 86% (n =35) "agreed" Or "strongly agreed". A similar proportion "agreed" or "strongly agreed" that improved standardized color labels would decrease the incidence of medication error (85. %, n = 34). 100% (n = 40) disagree that having all anesthetic-related drugs similarly labeled and packaged would reduce errors. 50 %(n=20) agree that strategies such as prefilled syringes would reduce the number of errors. (Orser, B. A. et.al (2001).

This result was in some part similar to study result found by orser *et al,* most anesthesiologists reported they reading the label, Most of the time(47.3%),Always(47.6%),and Sometimes (4.6 %),they also felt ,Color of text, label, vial, ampoule or cap(50.7%),Drug name or label (7.5%),Shape /Size of container (11.1%) can be most important feature used to identify drugs. they believed these labels decrease the incidence of drug errors,86.9% (n =597) they also "agreed" or "strongly agreed" that improved standardized color labels would decrease the incidence of medication error (83.8%, n = 576). Only 9.5% (n = 65) felt that having all anesthetic-related drugs similarly labeled and packaged would reduce errors Most participants did not agree that strategies such as prefilled syringes 17.3% (n = 119) would reduce the number of errors. (Orser, B. A. et.al (2001).

In the last part of our questioner, the majority of errors identified in the survey have been reported 74% (n = 29). Practitioners reported the errors to anesthesia physicians, attending staff at teaching centers or HOD. No errors were reported to provincial or national health agencies. When asked why the errors were not reported, the most common response was that the error was inconsequential (26%, N=11). Most patients (75%, n = 25) were not informed of the drug error. When asked, "If there were a single reporting agency for anesthetic drug errors, would you have reported the error(s) to this agency?" 33 respondents of 40 (87%) agreed that they would report the error.

This result was compared with the other study done by orser *et al,* the majority of errors identified in the survey have not been reported elsewhere 60.1% (n = 423). Practitioners reported the errors to colleagues (10.4%, n = 72), attending staff at teaching centers (10%, n =69) or at departmental meetings or rounds (7.5%, n =52). No errors were reported to provincial or national health agencies. When asked why the errors were not, the most common response was that the error was inconsequential (68.3%, n = 469). A further 18% (n = 122) of anesthesiologists were not certain where or to whom the error should be reported. A smaller number of practitioners cited medico-legal concerns (n = 40 6.0%) or concerns regarding the opinion of their colleagues (5.7%, n = 38). Most patients (83.5%, n = 867) were not informed of the drug error. When asked, "If there were a single reporting agency for anesthetic drug errors, would you have reported the error(s) to this agency?" 234 respondents of 507 (46.1%) agreed that they would report the error. It should be noted that the type of reporting program (e.g., anonymous versus mandatory, self-reporting was not defined in the surgery. (Orser, B. A. et.al (2001).

Conclusion

The results of this study showed male patients were listed more (n= 60(60%)) than the female patient (n=40(40%)), majority number of patients were in 19-55 years age group, general surgical was the common procedure (n=34,(34%)), The majority of reported incidents occurred among (ASA II risk ,n=57(57%)) patients .general anesthesia was the major rout administered for most of the patient.

In this study we found that, neuromuscular blocker (13.36%) and analgesics (12.9%) drugs were mostly used with anesthesia agents during surgery. Morphine (44.5%) was the major analgesics used in most of the surgery. we also founded that there is some drug-drug interaction between anesthetic drugs with each other and with other drugs used during of surgery. we founded that in 100 patients, interaction between isoflurane and fentanyl was the mostly drug-drug interaction(n=65(65%)).

We also founded that there were many factors which contributing in medication error of anesthesia; most anesthesiologists experienced at least one drug error. The commonest error was the misidentification of ampoule/vial,

(55%, n = 22) Most errors were of major consequence, however, serious morbidity and mortality resulted from clearly preventable events. These results support the development of improved standards for drug labels. Also, education of health care professional to identify proper drug to avoid adverse drug reactions.

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