



## INVASIVE PROCEDURE INDICATION AND ITS COMPLICATION IN ICU UNIT

Areej Alenzi<sup>1\*</sup>, Bandar A. Alghamdi<sup>2</sup>, Bader AL Shammari<sup>3</sup>, Maryam Alotaibi<sup>4</sup>, Abdullah Al-Anzi<sup>5</sup>, Mohammed ALatawi<sup>6</sup>, Abdullah Alshammari<sup>7</sup>, Mohammed Alreshidi<sup>8</sup>, Abdulrahman Al Subhi<sup>9</sup>, Mohammed AL Rashidi<sup>10</sup>, Majed Al-Shammari<sup>11</sup>, Fahad Al shammari<sup>12</sup>, Amani Alrashidi<sup>13</sup>, Mohammed alajlan<sup>14</sup>, Naif Alfadamah<sup>15</sup>, Manei Alrsheedi<sup>16</sup>, Saleh AL Rashidi<sup>17</sup>, Maryam Almutawa<sup>18</sup>, Mohammed almashhur<sup>19</sup>, Naif AL-Suwat<sup>20</sup>, Rashed alrashedi<sup>21</sup>

<sup>1\*</sup>Department of Infection Control and Public Health, Medical Forensic Services Center in Northern Border Region, ArAr 73211. Araalenzi@moh.gov.sa

<sup>2</sup>Senior Specialist-Public Health Infection Prevention & Control, Ministry of Health Office Bisha  
Bandar\_77\_b@hotmail.com

<sup>3</sup>Operating Room King Khalid Hospital in Hail BaSuAlshammari@moh.gov.sa

<sup>4</sup>Consultant neurosurgeon, King saud medical city Mrym.shebani@gmail.com

<sup>5</sup>Operating Room, King Khalid Hospital in Hail abshalanazi@moh.gov.sa

<sup>6</sup>General Practitioner king Fahad specialist hospital, tabuk Malatawi15@moh.gov.sa

<sup>7</sup>Operating Room, King Khalid Hospital in Hail Abbaalshammari@moh.gov.sa

<sup>8</sup>Operating Room, Maternity and Children's Hospital in Hail Mosaalreshidi@moh.gov.sa

<sup>9</sup>Operating Room King Khalid Hospital in Hail, aboalsubhi@moh.gov.sa

<sup>10</sup>Operating Room King Salman Hospital in Hail Mokhalrashdi@moh.gov.sa

<sup>11</sup>Operating Room Hail General Hospital madalshammari@moh.gov.sa

<sup>12</sup>Operating Room King khalid Hospital in Hafar Albatin falshammari86@moh.gov.sa

<sup>13</sup>Operation Room King Khalid General Hospital in Hafar Al-Batin Ammfalrashidi@moh.gov.sa

<sup>14</sup>Operation Room, King Khalid Hospital in Hail, Moalajlan@moh.gov.sa

<sup>15</sup>Radiology technician King khalid hospital in Hail Nalfadamah@moh.gov.sa

<sup>16</sup>Anesthesia technician King Khalid Hospital in Hail. Maneema@moh.gov.sa

<sup>17</sup>Anesthesia technician, King Khalid Hospital in Hail Salrashidi7@moh.gov.sa

<sup>18</sup>Nursing Specialist Omran General Hospital, rmohammed1415@gmail.com

<sup>19</sup>Opertaing Room, King khalid Hospital in Hail. Mhalmashhur@moh.gov.sa

<sup>20</sup>Ministry of Health Al sahan bani saad general Hospital. nsalsuwat @moh.gov.sa

<sup>21</sup>ERADA COMPLEX&MENTAL, HEALTH-HAIL, 10RN0307760, Rashed-030@hotmail.com

### Abstract

Invasive procedures are essential elements of patient care in intensive care units (ICUs), frequently utilizing medical equipment such as central venous catheters, endotracheal tubes, and mechanical ventilators. These operations, although life-saving, have considerable dangers, including infections, human error, and other problems that may prolong ICU admissions and elevate fatality rates. This study sought to examine the competence of ICU medical personnel during invasive procedures, determine the prevalence and nature of problems, and evaluate patient perceptions on the informed consent process. The study, conducted at Al-Khums Teaching Hospital and Tripoli University Hospital, employed a cross-sectional questionnaire directed at 44 ICU physicians and surveyed patients to collect data on demographic features, procedural knowledge, complications, and informed consent practices. The findings indicated a significant degree of knowledge and excellent practice

among staff, with 84.09% exhibiting skill in airway suction and central line maintenance. Infections (75%) and human errors, including invasive device dislodgment (38.6%), were prevalent consequences. The study also identified deficiencies in the informed consent procedure, since numerous patients expressed a desire for additional information regarding risks and treatment options. The findings highlight the necessity for ongoing training for ICU personnel, consistent protocols for invasive treatments, and enhanced communication during informed consent to improve the quality and safety of patient care.

**Keywords:** Invasive procedures, ICU complications, patient safety, informed consent, medical staff training.

## **Introduction**

Medical staff at intensive care units (ICUs) face unique challenges due to the nature of the care they provide, the complexity of the patients' conditions, the number of staff members required, and the involvement of consultants from a wide range of medical fields [1].

Patients who are critically sick are those who are in imminent danger of dying and hence need round-the-clock care from medical professionals and often rely heavily on medical equipment. Every day in the ICU, numerous medical procedures are carried out on critically ill patients. Complications are still a common occurrence, and some of them can be fatal. Common ICU support and monitoring devices include intravenous catheters, nasogastric tubes, endotracheal tubes, central venous catheters, hemodialysis double-lumen catheters, and chest tubes. Complications during surgical procedures involving seriously ill patients are widespread and frequently life-threatening. Reducing the incidence of problems during procedures is an essential and straightforward method for raising care standards. Controlling the damage requires knowledge of their prevalence, causes, risk factors, diagnosis, therapy, and prevention [2].

Two types of procedures exist: invasive procedures and non-invasive procedures. Any medical technique that involve puncturing the skin is considered an invasive procedure. Any medical technique that doesn't involve puncturing the skin is considered a non-invasive procedure. Bleeding, infection, adhesions, internal organ injury, blood vessel injury, venous or pulmonary blood clot, breathing issues, and mortality are all possible risks and complications of minimally invasive treatments, just as they are with any other type of surgical surgery. The increased exposure to cold, dry gases during insufflation may raise the risk of hypothermia and peritoneal damage [3].

Every day in the ICU, numerous medical procedures are carried out on critically ill patients. In spite of this, it is clear that problems still occur often and can have fatal consequences. Common ICU support and monitoring devices include Intra-arterial catheters, intravenous catheters, nasogastric tubes, endotracheal tubes, central venous catheters, hemodialysis double-lumen catheters, and chest tubes.

In rare cases, patients may experience difficulties following medical operations. This is especially true when the medical device is implanted, surgically implanted, or put into a body cavity, the blood stream, the gastrointestinal tract, or the body itself. Symptoms of complication can appear right after insertion, or they can show up later [4].

## **Aim of study:**

In this questionnaire survey, we aimed to examine how well the medical staff performed during invasive operations and learn more about the frequency, nature, and severity of complications experienced by ICU patients following invasive procedures. To further investigate, we inquired into the medical staff' degrees of assurance while carrying out these operations. Evaluation of patient attitudes towards the informed consent process for invasive procedures, including a description of patients' experiences with and reactions to information about the risks of the procedure and their alternatives, as well as an evaluation of the informed consent process as a whole.

**Objectives of the study:**

To provide an overview of the reported indication of the invasive procedure and its complication in ICU unit.

**The research problem:**

Invasive procedures are essential parts of medical care. The lack of assessing risk factors related to the infection or injuries practices induced from invasive procedures professionals and equipment sterilization methods by health. It is important to identify factors associated with invasive procedures indication and complications among patients admitted at ICU unit.

**Methodology****1. Study Design**

Al-Khums Teaching Hospital and Tripoli University Hospital were surveyed using a cross-sectional questionnaire. Participants were asked to fill out a questionnaire on their demographic information as well as their familiarity, perspective, and behavior surrounding invasive procedures and its complication.

**2. Participants**

The survey participants were all ward doctors from ICU unit in Al-Khums Teaching Hospital and Tripoli University Hospital (N=44) These hospitals were a convenient sample of medium to large general acute care hospitals because they had over 300 beds. All hospital ward doctors were asked to participate in the study. The minimum number of responses per item included in a factor analysis was three, and this number was used to establish the size of the sample. Patients had to be 18 years or older and have survived an ICU stay of at least three full days. Patients who died, were in trusteeship, were deemed to have insufficient mental capacity by the bedside ICU doctor, could not comprehend English well enough to complete the questions, or were transferred to another ICU while on MV were not included in the study.

**3. Study Tool**

A questionnaire survey was given out by hand to random doctors of Al-Khums Teaching Hospital and Tripoli University Hospital The questionnaire study was designed to focus on invasive procedures and its complication, also this study included questions for patients. A survey tool was created to investigate doctors' levels of knowledge, attitudes and practice about invasive procedures and its complications in ICU unit.

There were 65 validated inquiries on the survey. The first section had 4 questions total about the demographic characteristic of the study sample; age, sex, academic qualification and years of intensive care experience.

The second section had 11 questions total for the baseline characteristics of study respondents, characteristics of the ICUs, type of institution, type of intensive care, number of intensive care beds, total number of admissions a year, patients gender, co-morbidities, admission source, times of ICU admission during hospitalization, invasive procedures during hospitalization per chronic disease for patients in ICUs, and treatments during hospitalization per chronic disease for patients in ICUs.

The third section comprise 8 questions about characteristics of patients admitted during the study, the questions were multiple choice questions include; number of admissions, patients' age, sex, operative status, admission status, days spent in days, types of complications and human error causing these complications.

The fourth section had 9 questions about knowledge regarding invasive procedures in intensive care unit include; general information about invasive procedures were satisfactory or not, general knowledge about complications of invasive procedures, respondents' role regarding invasive procedures, the level of training scale range from (good, very good, excellent), respondents worked at public hospital or private hospital, confident level when performing invasive procedure, and obtaining certified training courses.

The fifth section had 4 questions discuss about number and percentage distribution of respondents according to their total level of practice regarding invasive procedures in intensive care unit, the answers consisted of satisfactory and unsatisfactory choices.

The sixth section had 10 questions discuss about procedural features of invasive procedures performed in the intensive care unit which include; who performed invasive procedures in ICU, most frequent indication for the invasive procedures, reasons for tracheotomy, most frequent timing of invasive procedures, MV indications, sedation-analgesia-neuromuscular blocking protocol should be provided or not, local anesthesia provided or not, early and late complications of most frequent intraprocedural complication, most frequent early complication, and most frequent late complication.

The seventh section had 8 questions discuss about procedural features of arterial line invasive procedures in the intensive care unit include; arterial catheter insertion or replacement need informed consent or not, who performed arterial line invasive procedures in ICU, indications for arterial line, contraindication for arterial catheterization use present or not, the most frequent contraindication for arterial catheterization in ICU, the most frequent complications of arterial catheters in ICU, and time needed for arterial catheters be changed.

The section eight had 11 questions discuss about patients if they had received an explanation about alternative options for this treatment, to be involved in the decision on the treatment, who get him most of the explanations and degree of satisfaction about decision making for the treatment. The purpose of this inquiry is to assess the degree to which the healthcare provider is conversant with invasive procedures and its complications in ICU unit. For the record, the questionnaire was written in English.

#### **4. Ethical issues**

University of Tripoli research and ethical committee approved the study. The administration of the hospital granted us permission to conduct interviews with patients. The researcher guarantees that all subject information will be kept private and anonymous. All participating respondents were advised that their participation was voluntary and that they might terminate their participation at any moment. The respondents who agreed to take part in the study did so by giving their verbal consent. All individuals gave their agreement after receiving adequate information about the risks involved. Patients were promised that their responses would be kept private and that only summary results would be shared with their healthcare providers, thus their participation was entirely optional.

#### **5. Data collection procedure**

The researchers briefed the hospital directors on the study's rationale. After supervisors in the ICU department consented to take part, they were instructed to send questionnaires on to their ward doctors. After agreeing to take part in the study, ward doctors filled out questionnaires about their practices and returned them to the researchers in sealed envelopes. Age, sex, reason for ICU admission, location prior to ICU, and category of main diagnosis were all collected from doctors about patients in the ICU. Length of stay in the hospital and in the unit under study. Mechanical ventilation, central venous catheter, chest tube, indwelling urethral catheter, Other invasive procedures and therapy were all noted, along with the total number of days spent in the ICU for the patients. It was noted whether or not the major procedures known to cause pain or discomfort were performed during the ICU stay. Data on whether the procedures were carried out using what type of invasive procedures was gathered. Analysis of the doctors' daily workload based on an evaluation of monitoring and controls, respiratory support, cardiac support, renal support, metabolic support, and particular intervention conducted both within and outside the ICU. Mechanical ventilation, central venous catheter, peripheral venous catheter, urine catheter, surgery, drainage, dialysis, endoscopy, bronchoscopy, complete parenteral nutrition, and enteral feeding were all invasive procedures used during hospital stays in the units under review. In addition, the total number of days that these methods were used was analyzed.

An unintended and unfavourable condition that developed as a direct result of medical treatment and had nothing to do with the underlying sickness or condition of the patient was classified as a

complication of care, drugs or a surgical procedure could be the cause. If medical care was changed because of an infection caused by an invasive medical equipment, it was thought that an infection had occurred. Some of the factors taken into account by the ICU care team while making clinical diagnosis were: First, an infection caused by the catheter itself or caused by the ventilator or an infected wound has a temperature higher than 38 degrees, shows signs of local inflammation, and/or has a positive wound culture. According to the aforementioned criteria, clinical deterioration was determined to have happened if the patient's health deteriorated in a way that was consistent with a complication. Major, moderate, or small severity of complications was identified. Complications were classified as significant if they threatened the patient's life or if they required treatment that was only available in the ICU, moderate if they required treatment that was more commonly available, and minor if they went away on their own. Human errors were classified as either technical, judgement, or monitoring/vigilance failures. A patient's condition or an event that occurs during treatment does not necessarily indicate negligence or a departure from the appropriate standard of care.

The effectiveness of patient-doctor communication was also assessed. Test-retest reliability was determined by having ward doctors from five hospitals fill out the questionnaire twice, two weeks apart. Participants did not engage in any formal schooling or training for the course of the two-week period.

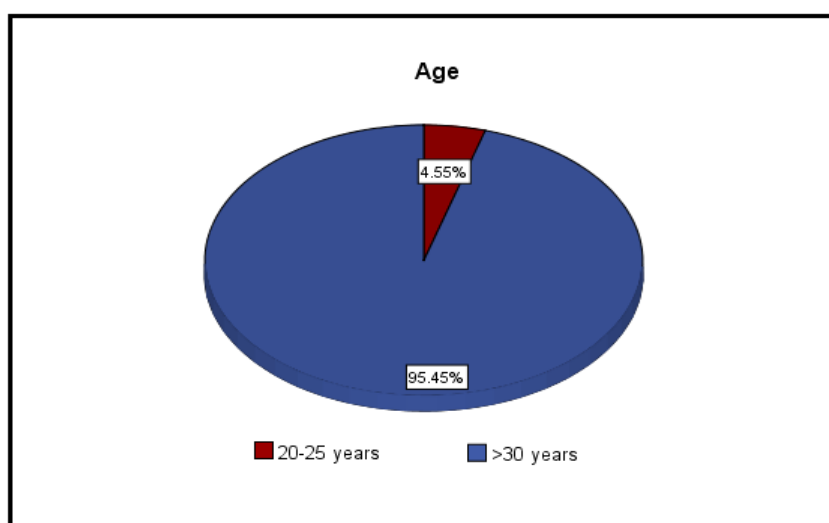
## 6. Statistical analysis

The data was processed with SPSS (Statistical Program for the Social Sciences) (SPSS 22; IBM Corp., New York, NY, USA). Categorical variables were expressed as percentages, and continuous variables were presented as means and standard deviations. Testing was performed using the T-test for continuous variables and the Chi-square test for categorical variables. The significance level for the t test was set at  $p < 0.05$ .

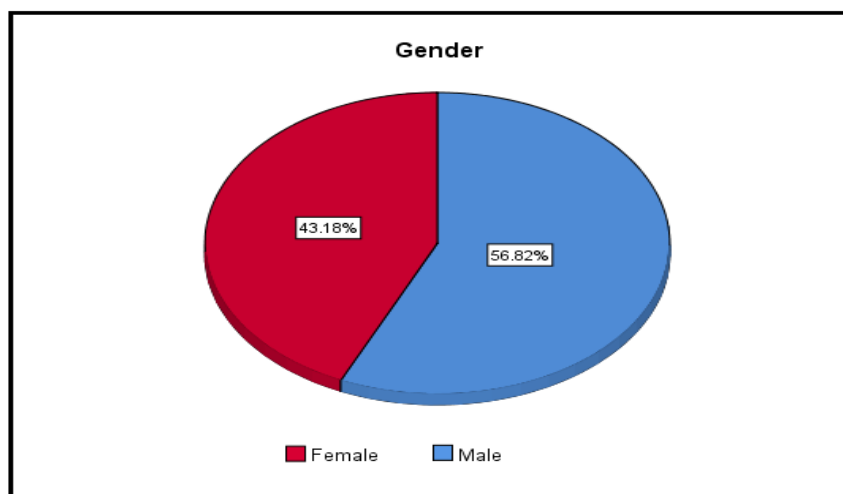
## Results

### 1. Participant characteristics:

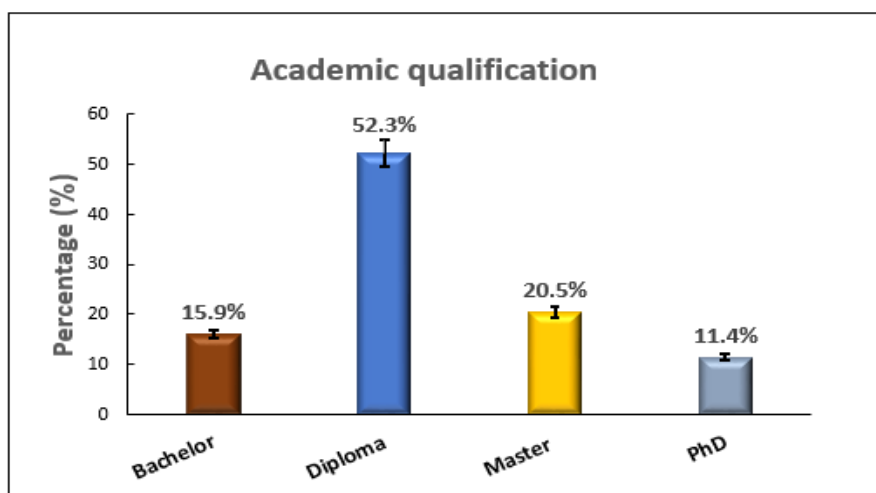
The survey was distributed over 44 ICU doctors in Al-Khums Teaching Hospital and Tripoli University Hospital. The age of the most participants ( $SD = 0.421$ ) was as follow; 20-25 years (4.55%), >30 years (95.45%) (**Figure 1**). The gender of participants ( $SD = 0.501$ ) was female (43.18%) and males (56.82%) (**Figure 2**). The majority of them had diploma degree (52.3%), followed by master (20.5%), bachelor (15.9%) and PhD degree (11.4%) with  $SD = 0.872$  (**Figure 3**). Most participants had 5-10 years of experience in ICU (63.64%), while 36.36% had experience in ICU less than 5 years with  $SD = 0.487$  (**Figure 4**).



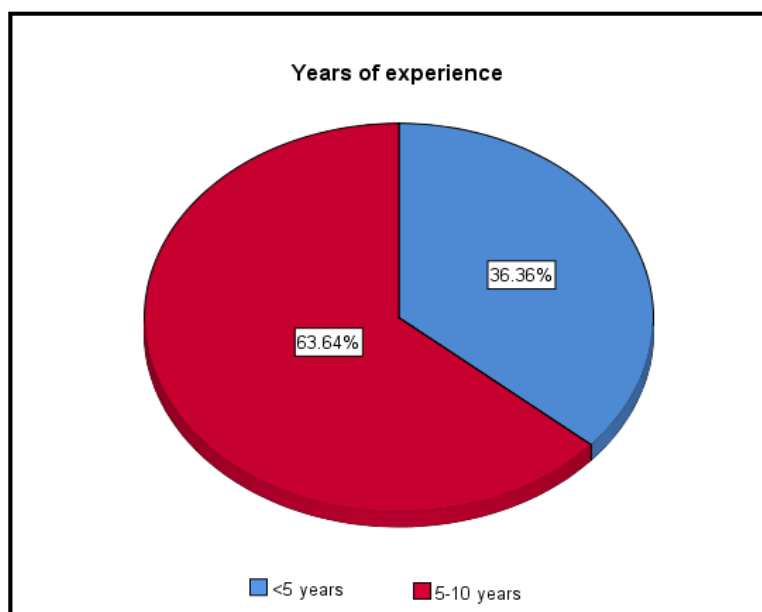
**Figure 1. Percentage of age category.**



**Figure 2. Percentage of gender category.**



**Figure 3. Percentage of academic qualification category.**



**Figure 4. Percentage of years of experience category.**

## 2. Baseline characteristics:

**Table (1)** showed that most of the participants' specialty area was in intensive care (65.9%), followed by cardiology (18.2%), other area (9.1%), then anesthesiology (6.8%). Type of institution was 88.6% public hospital, 4.5% private hospital, and 6.8% university hospital. The type of intensive care at which participants work was as follow 20.5% was cardiac ICU, 13.6% medical ICU, 9.1% surgical ICU and 56.8% mixed type ICU. 90.9% of the participants responded that the number of beds in ICU in their hospitals were less than 10 and 9.1% were between 11–19 beds. Most of the participants responded that number of patients admitted to the ICU were less than 300 patients (65.9%), followed by 301–600 (18.2%), 601–999 (9.1%), and  $\geq 1000$  (6.8%), while 84.1% of these patients were male and 15.9% were females with 48.9% diabetes comorbidities, 13.6% hypertension comorbidities and 34.1% with other comorbidities. Admission source of most patients was from emergency department (45.5%) followed by other hospitals (36.4%) and hospital wards (18.2%). Respondents found that the rates of admission of patients in ICU 70.5 % were more than once. The invasive procedure during hospitalization per chronic disease for patients in ICUs was mechanical ventilation (18.2%), central venous catheter (22.7%), indwelling urethral catheter (9.1%), and other types (50%). Treatments used during hospitalization per chronic disease for patients in ICUs were antibiotic (56.8%), fluid resuscitation (31.8) and vasoactive drugs (11.4%).

**Table 1.** Baseline characteristics of ICU and patients.

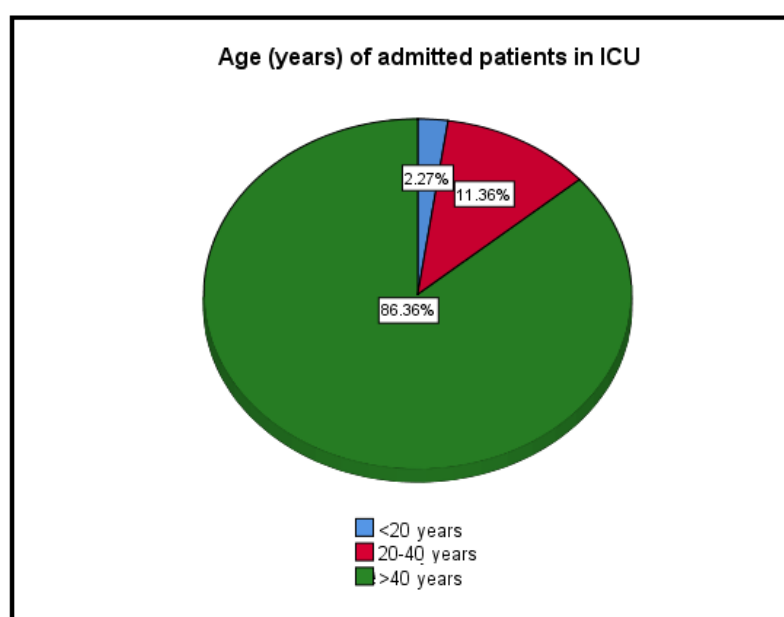
	Responses number	Responses %	Standard deviation	P value
Main specialty area				
- Intensive care	29	65.9	1.928	0.001*
- Anesthesiology	3	6.8		
- Cardiology	8	18.2		
- Other	4	9.1		
Type of institution				
- Public hospital	39	88.6	0.540	0.009
- Private hospital	2	4.5		
- University hospital	3	6.8		
Type of intensive care				
- Cardiac	9	20.5	1.069	<0.001*
- Mixed	25	56.8		
- Medical	6	13.6		
- Surgical	4	9.1		
Number of ICU beds				
- ≤ 10	40	90.9	0.291	0.016
- 11–19	4	9.1		
Number of patients/years admitted in ICU				
- ≤300	29	65.9	0.925	0.002*
- 301–600	8	18.2		
- 601–999	4	9.1		
- ≥1000	3	6.8		
Patients gender				
- Male	37	84.1	0.370	0.001*
- Female	7	15.9		
Comorbidities				
- Diabetes	23	52.3	1.380	<0.001*
- Hypertension	6	13.6		
- Other	15	34.1		
Admission source				

- Hospital wards	8	18.2	0.724	<0.001*
- Emergency department	20	45.5		
- Other hospitals	16	36.4		
Times of ICU admission during hospitalization				
- Once	13	29.5	0.462	<0.001*
- More than one	31	70.5		
Invasive procedures during hospitalization per chronic disease for patients in ICUs				
- Mechanical ventilation	8	18.2	1.691	0.001*
- Central venous catheter	10	22.7		
- Indwelling urethral catheter	4	9.1		
- Other	22	50		
Treatments during hospitalization per chronic disease for patients in ICUs				
- Antibiotic	25	56.8	0.697	0.002*
- Fluid resuscitation	14	31.8		
- Vasoactive drugs	5	11.4		

\* Significant p value

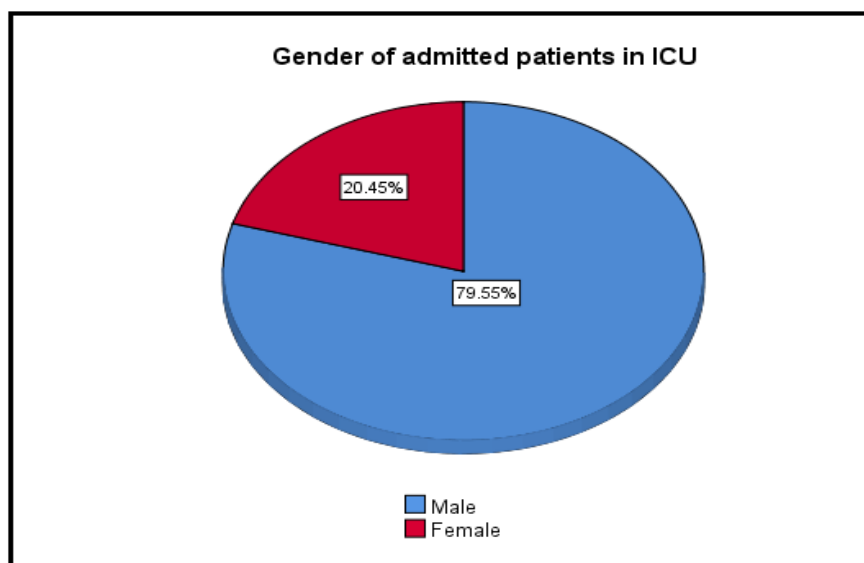
### 3. Characteristics of patients admitted during the study and complications related

Patients age admitted to ICU during the study mostly was over 40 years (86.63%, SD=0.428, P=0.003) (**figure 5**), and most of them were male (79.5%, SD=0.408, P=0.104) (**figure 6**). Patients admitted during this study more than once (84.1%, SD=0.370, P=0.03) (**figure 7**). Most of the patients were from non-operative status (77.3%, SD=0.404, P=0.001) (**figure 8**). The admission status was emergency (61.4%) and elective (38.6%) with SD= 0.493 and P value= <0.001 (**figure 9**). Patients admitted for 2-5 days mostly (65.9%), while some admitted for less than two days (20.5%) and other for five days (13.6%) with SD= 0.587 and P value= 0.383 (**figure 10**). The types of complication patients suffered from were as follow, ventilator related (9.1%), postextubation stridor (2.3%), infections (75.0%), drug related (9.1%), and procedure related (medical surgical) (4.5%) with SD= 0.821 and P value= 0.001 (**figure 11**). Human error causing these complications ranged from accidental extubations (13.6%), medication error (6.8%), intravenous fluid error (4.5%), invasive device dislodged from patient (38.6%), and procedure related (36.4%) with SD= 1.379 and P value= 0.002 (**figure 12**).

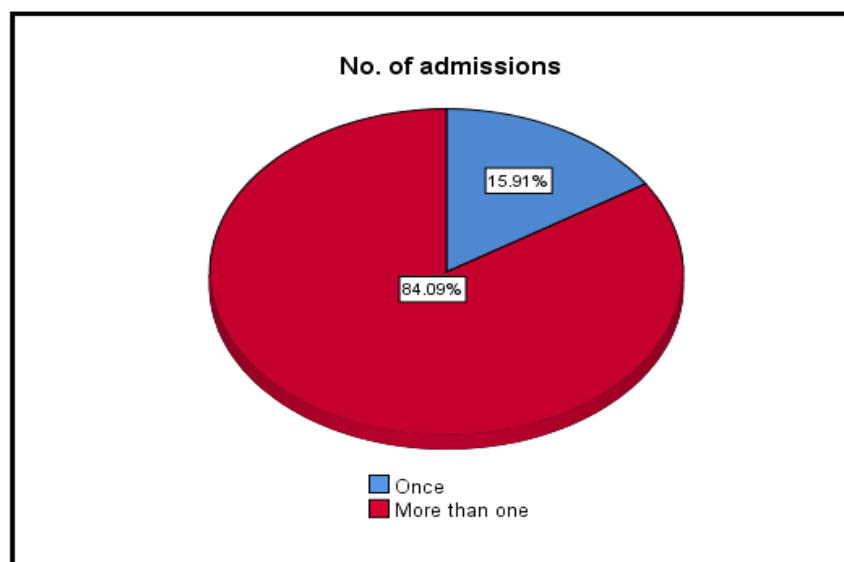


**Figure 5. Percentage of age category of patients during the study.**

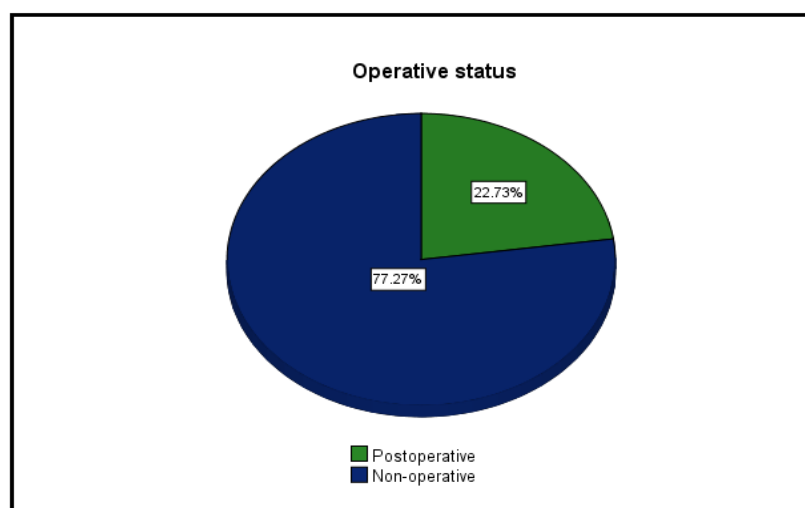




**Figure 6. Percentage of gender category of patients during the study.**



**Figure 7. Percentage of admission rate of patients during the study.**



**Figure 8. Percentage of operative stage of patients during the study.**

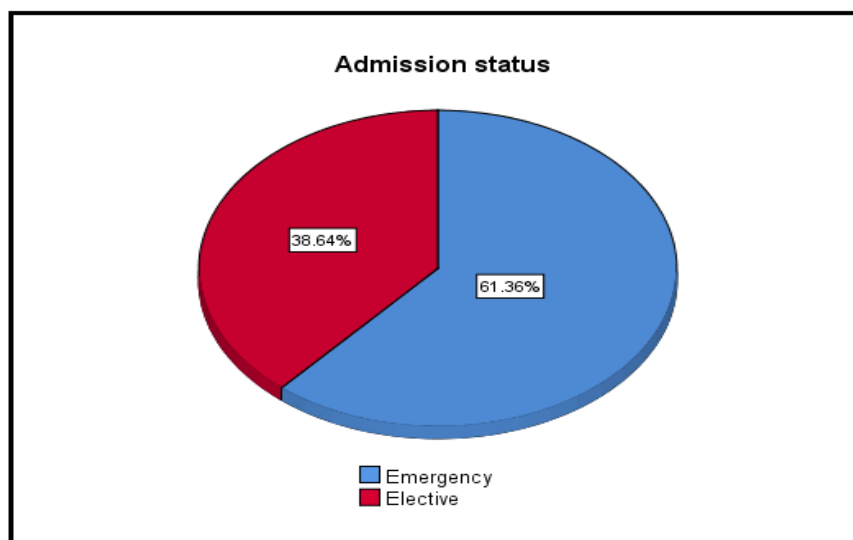


Figure 9. Percentage of admission status of patients during the study.

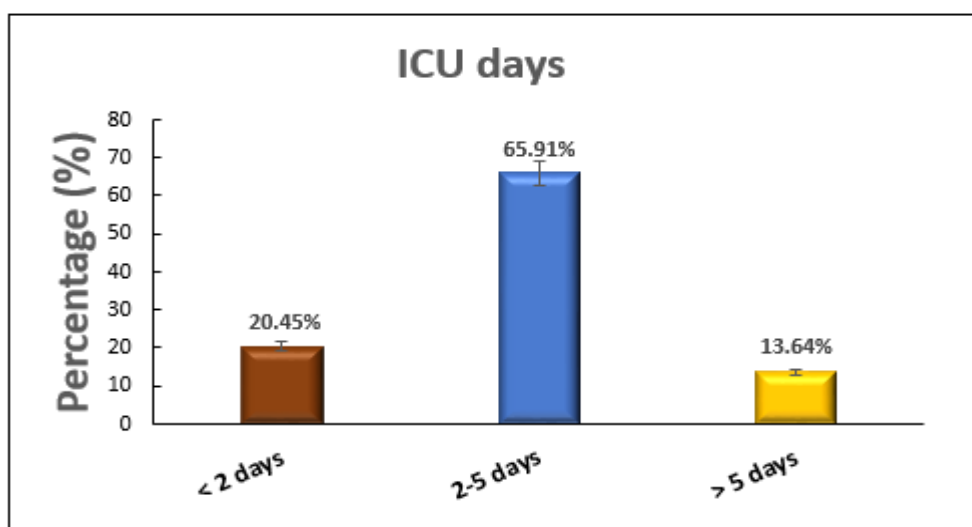


Figure 10. Percentage of ICU days at which patients spent during the study.

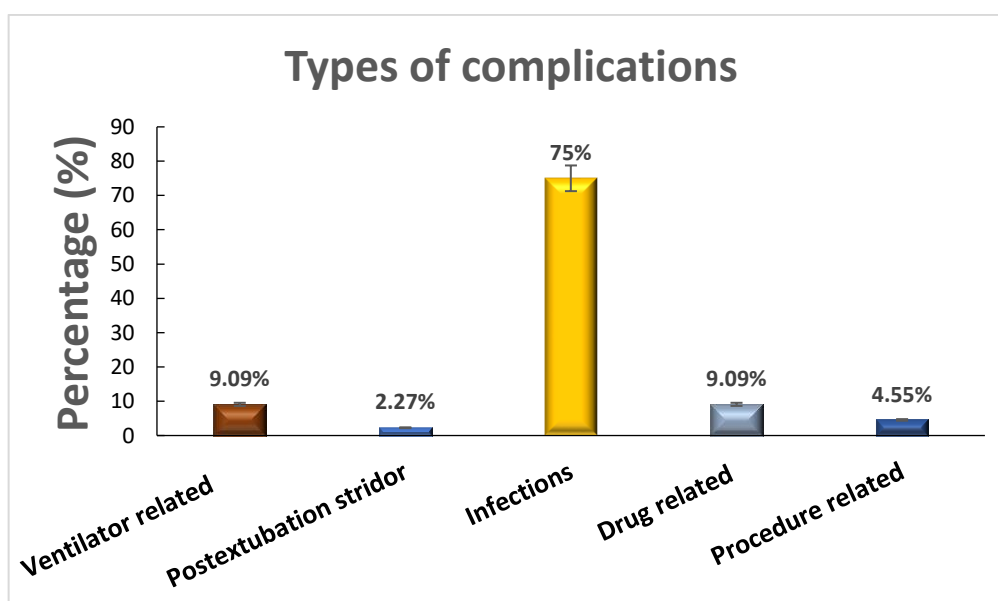


Figure 11. Percentage of types of complications which patients suffer.

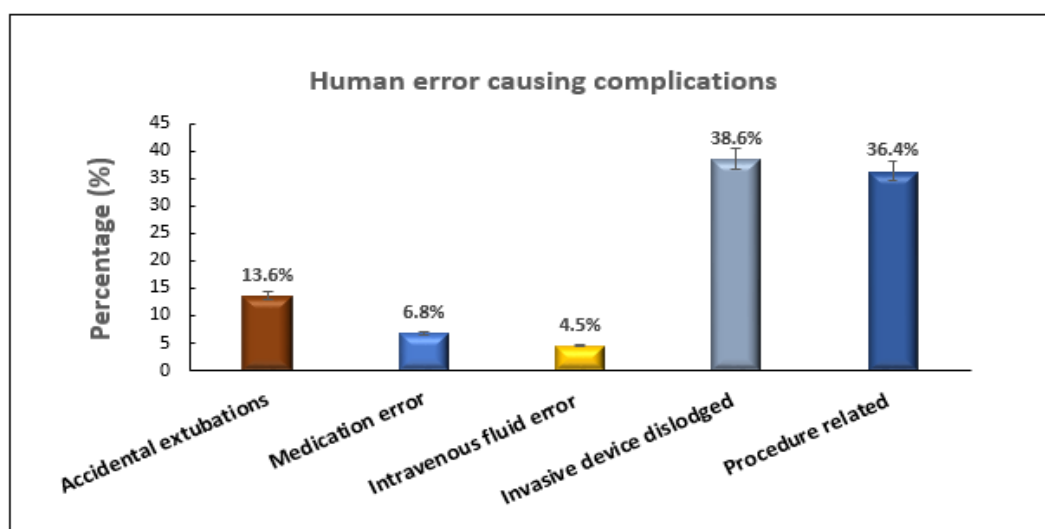


Figure 12. Percentage of human errors causing complications.

#### 4. Knowledge regarding invasive procedures in ICU:

**Table (2)** presented that, there was statistically significant level of knowledge about the complication of the respondents (P value= 0.001). Also, there was statistically significant level with their confident when performing invasive procedure (P value= <0.001). There was statistically significant level with training course (P value= <0.001). While there was no significant level with general information about invasive procedures (P value= 0.07). Respondents were satisfied about their role regarding invasive procedures such as endotracheal tube, suction, and central venous catheterization by 93.2%. Most of respondents worked at public hospitals by 95.5%. There were 86.4% of the respondents performed invasive procedures before and 90.9% of them attained certified training course before.

**Table 2.** The level of knowledge about invasive procedure in ICU and its complications (n=44).

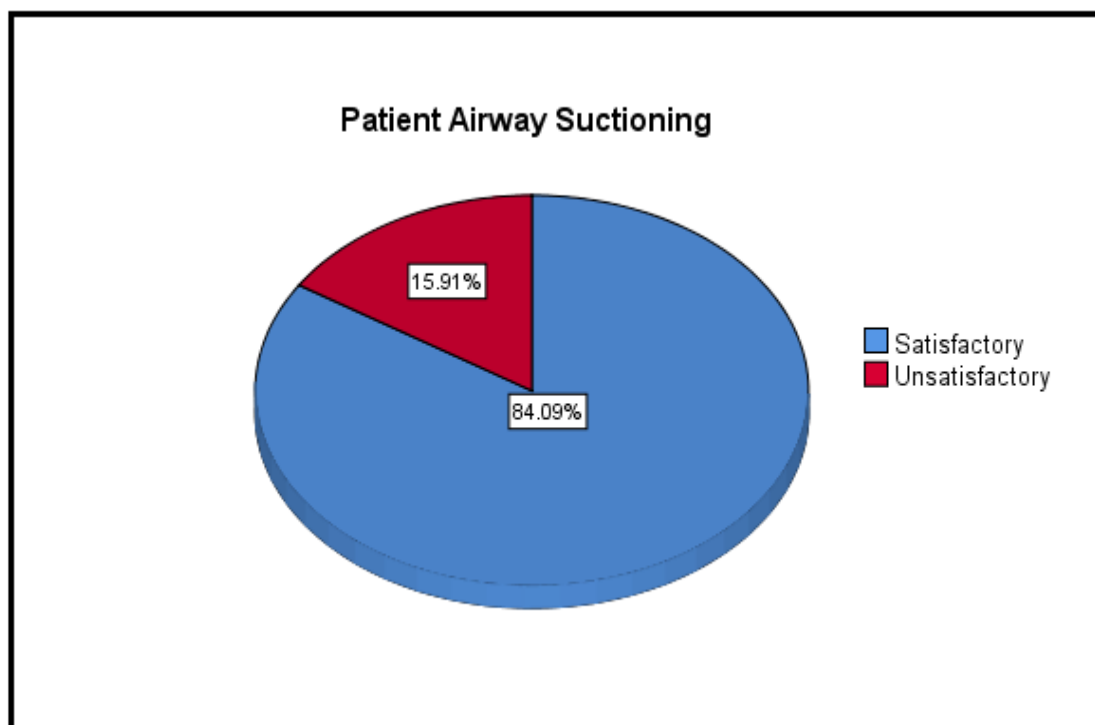
	Responses number	Responses %	Standard deviation	P value
General information about invasive procedures				
- Satisfactory	40	90.9	0.291	0.07
- Unsatisfactory	4	9.1		
Complications of invasive procedures				
- Satisfactory	35	77.3	0.424	0.001*
- Unsatisfactory	9	22.7		
Respondents' role regarding invasive procedures: Endotracheal tube, Suction, Central venous catheterization				
- Satisfactory	41	93.2	0.255	0.120
- Unsatisfactory	3	6.8		
What level of training are you?				
- Good	15	34.1	0.518	<0.001*
- Very good	28	63.6		
- Excellent	1	2.3		
At which Hospitals have you worked?				
- Public hospital	42	95.5	0.211	0.101
- Private hospital	2	4.5		
Please choose if you have worked in any of the following Specialties:				
- A&E	25	56.8	0.697	<0.001*
- Intensive Care Unit	14	31.8		

- Acute Medicine/AAU	5	11.4		
Have you performed invasive procedures before?				
- Yes	38	86.4	0.347	0.021
- No	6	13.6		
How confident are you at performing this procedure?				
- Not confident	4	9.1	0.568	<0.001*
- Very confident	29	65.9		
- Unsupervised	11	25.0		
Have you attended any certified training courses?				
- Yes	40	90.9	0.291	0.007
- No	4	9.1		

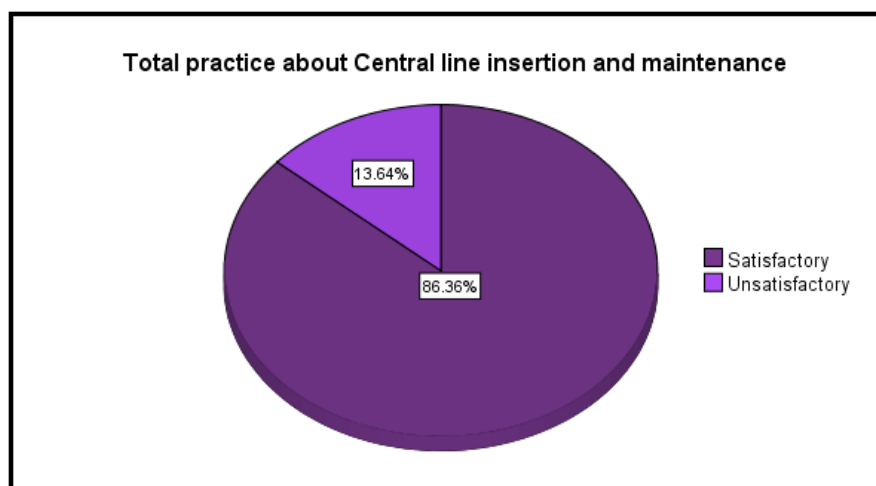
\* Significant p value

### 5. Number and percentage distribution of respondents according to their total level of practice regarding invasive procedures in intensive care unit:

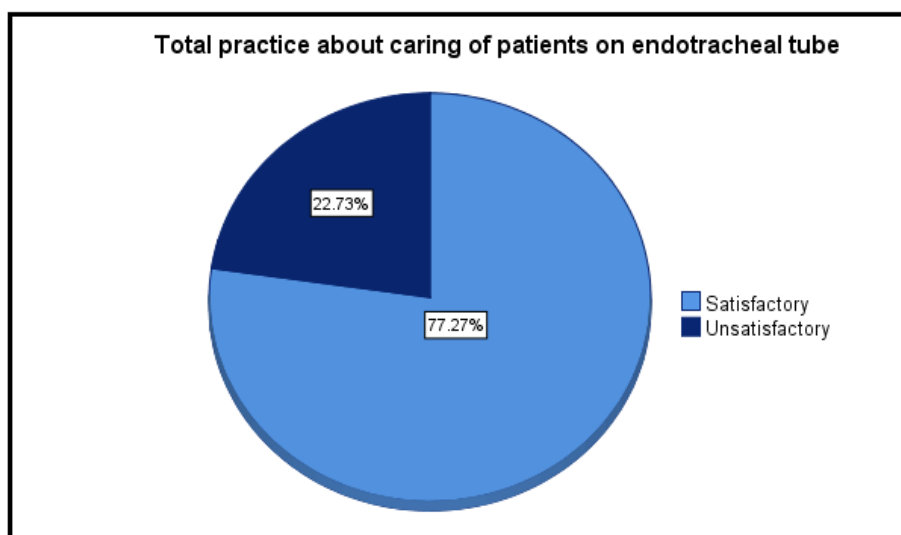
The following figures illustrated the studied respondents' total practice level regarding invasive procedures in intensive care unit, it was found that 84.09% of them had satisfactory total level of practice regarding invasive procedures (airway suction) in intensive care unit, while 15.91% of them had unsatisfactory practice (SD=0.370). 86.63% were satisfied about total practice of central line insertion and maintenance, while 13.64% were unsatisfied (SD=0.347). 77.27% were satisfied about total practice of caring of patients on endotracheal tube while 22.73% were unsatisfied (SD=0.424). 70.45% were satisfied about total practice regarding invasive procedures in intensive care unit while 29.55% were unsatisfied (SD=0.462).



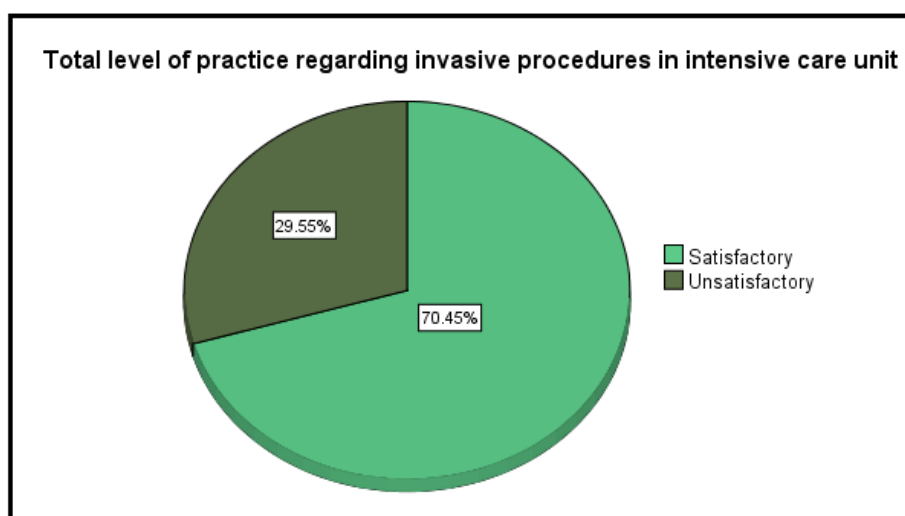
**Figure 13. Percentage of satisfactory level about airway suction.**



**Figure 14. Percentage of satisfactory level about total practice of central line insertion and maintenance.**



**Figure 15. Percentage of satisfactory level about caring of patients on endotracheal tube.**



**Figure 16. Percentage satisfactory level about total practice regarding invasive procedures in intensive care unit.**

**6. Procedural features of invasive procedures performed in the ICU:**

**Table (3)**, revealed that the most staff performed invasive procedures in ICU were doctors with 68.2% and SD=1.769. The most frequent indications for invasive procedures were improvement of patient respiratory mechanics (36.4), inability to cough and swallow (34.1), and difficult/prolonged weaning (25%,) with SD=1.255. Reasons for tracheotomy were for anticipation of prolonged MV (25%), prolonged MV more than 14 days (36.4%), and airway stenosis (38.6%) with SD= 0.795. Most frequent timing of invasive procedures was less than 10 days (61.4%). Mechanical ventilation mostly used for minute volume/adaptive support ventilation. 59.1% of the respondents agreed that sedation analgesia neuromuscular blocking protocol provided in ICU. 52.3% disagreed that local anesthesia provided. The earliest and late complications of most frequent intraprocedural complication were other reasons (65.9%, 70.5%) than mentioned in the questionnaire.

**Table 3.** Features of invasive procedures performed in the ICU.

	Responses number	Responses %	SD	P value
<b>Who performed invasive procedures in ICU</b>				
- Doctors	30	68.2	1.769	<0.001*
- Anesthesiologist	4	9.1		
- Other	10	22.7		
<b>Most frequent indication</b>				
- Prolonged mechanical ventilation	1	2.3	1.255	0.001*
- Difficult/prolonged weaning	11	25.0		
- Neurocritical disease	1	2.3		
- Inability to perform airway protection	15	34.1		
- Inability to cough and swallow	16	36.4		
<b>Reasons for tracheotomy</b>				
- Anticipation of prolonged MV	11	25.0	0.795	0.004*
- Prolonged MV more than 14 days	16	36.4		
- Airway stenosis	17	38.6		
<b>Most frequent timing of invasive procedures</b>				
- <10 days	27	61.4	0.627	<0.001*
- 11–20 days	14	31.8		
- >20 days	3	6.8		
<b>Mechanical ventilation mostly used</b>				
- Volume control ventilation	8	18.2	1.455	0.001*
- Minute volume support ventilation	15	34.1		
- Bilevel airway pressure	5	11.4		
- Other	16	36.4		
<b>Sedation analgesia neuromuscular blocking protocol provided in</b>				
- Yes	26	59.1	0.497	<0.001*
- No	18	40.9		
<b>Local anesthesia provided</b>				
- Yes	21	47.7	0.505	0.001*
- No	23	52.3		
<b>Early and late complications of most frequent intraprocedural complication</b>				
- Puncture posterior tracheal wall	1	2.3	2.805	0.003*
- Puncture ETT	3	6.8		
- Accidental extubation	7	15.9		
- Difficult cannula placement	1	2.3		
- Stoma not adequate	1	2.3		
- False passage	3	6.8		
- Bleeding controlled by compression	4	54.5		

- Other	24	24		
<b>Most frequent early complication</b>				
- Accidental extubation	1	2.3	2.192	0.005*
- Difficult cannula placement	2	4.5		
- False passage	3	6.8		
- Bleeding controlled by compression	5	11.4		
- Desaturation	1	2.3		
- Pneumothorax	2	4.5		
- Emphysema	1	2.3		
- Other	29	65.9		
<b>Most frequent late complication</b>				
- Bleeding requiring exploration	1	2.3	0.876	<0.001*
- Stoma infection/inflammation	8	18.2		
- Cannula extraction/malpositioning	4	9.1		
- Other	31	70.5		

\* Significant p value

### 7. Procedural features of arterial line invasive procedures in the intensive care unit:

**Table (4)**, demonstrated that 88.6% of the respondents believed arterial catheter insertion or replacement need informed consent with SD= 0.32. The most staff performed arterial line invasive procedures in ICU were doctors with 81.8% and SD=1.38. 52.3% of the respondents verified pulsatile blood flow indicate correct placement of the catheter with SD=0.50. 56.8% of the respondents assessed the arterial line for continuous monitoring of blood pressure, cardiovascular effects of vasoactive drugs, frequent arterial blood gas and laboratory sampling with SD=1.47. most of the respondents (84.1%, SD=0.37) believed that there is contraindication for arterial catheterization use. The most frequent contraindication for arterial catheterization respondents face in ICU was infection at the site of insertion (79.5%, SD=0.63). The most frequent complications of arterial catheters respondents found in ICU was hematoma formation (54.5%, SD=1.15). 52.3% of the respondents believed that arterial catheters should be changed every 96 hours, while 34.1% believed that arterial catheters should be changed every 24 hours.

**Table 4.** Features of arterial line invasive procedures performed in the ICU.

	Responses number	Responses %	SD	P value
<b>Do you believe arterial catheter insertion or replacement need informed consent?</b>				
- Yes	39	88.6	0.32	0.006
- No	5	11.4		
<b>Who performed arterial line invasive procedures in ICU</b>				
- Doctors	36	81.8	1.38	0.001*
- Anesthesiologist	4	9.1		
- Other	4	9.1		
<b>How do you verify arterial line placement?</b>				
- Pulsatile blood flow	23	52.3	0.50	<0.001*
- Absence of blood flow	21	47.7		
<b>What do you assess with an arterial line?</b>				
- Continuous monitoring of blood pressure	4	9.1	1.47	<0.001*
- Cardiovascular effects of vasoactive drugs	7	15.3		
- Frequent arterial blood gas	5	11.4		
- Laboratory sampling.	3	6.8		
- All of the above	25	56.8		
<b>Is there a contraindication for arterial catheterization use?</b>				

- Yes	37	84.1	0.37	0.001*
- No	7	15.9		
What is the most frequent contraindication for arterial catheterization you face in ICU?				
- Peripheral or distal arterial vascular insufficiency	4	9.1	0.63	<0.001*
- Peripheral arterial vascular diseases	5	11.4		
- Infection at the site of insertion	35	79.5		
-What are the most frequent complications of arterial catheters you found in ICU?				
- Temporary vascular occlusion	4	9.1	1.15	0.005*
- Thrombosis	6	13.6		
- Ischemia	5	11.4		
- Hematoma formation	3	54.5		
- Infection and sepsis	24	11.4		
How often should arterial catheters be changed?				
- 24 hours 15	15	34.1	0.92	0.005*
- 48 hours 6	6	13.6		
- 96 hours 23	23	52.3		

\* Significant p value

### 8. Patient perspectives on the informed consent process, including their level of comfort with it, the clarity of the information provided regarding potential harms and benefits, and the availability of other options:

**Table (5)**, showed that 97.7% of the patients signed an informed consent with SD= 0.15. 79.5% of the patients received an explanation about the risks from the treatment with SD=0.78. 97.7% of the patients wanted more explanation on these risks with SD=0.15. 72.3% of the patients received an explanation about alternative options for the treatment with SD=0.68. Half of the patients (45.5%) believed that the medical staff decides what is best for them and the other got explanations and decided what is best for them (43.2%) with SD=0.95. 72.7% of the patients felt that they were involved enough in the decision on their treatment with SD=0.52. The patients thought that they got short time explanations before treatment (54.5%) and 59.1% of the patients reported that the clinic doctor was the one who give them the explanations. Most of the patients were on a private medical service (81.8% SD=0.39). 72.7% of the patients felt free to ask questions. 61.4% % of the patients felt satisfied from the process of decision making for the treatment.

**Table 5.** Patient perspectives on the informed consent process.

	Responses number	Responses %	SD	P value
Have you signed an informed consent?				
- Yes	43	97.7	0.15	<0.001*
- No	1	2.3		
Did you receive an explanation about the risks from the treatment?				
- Yes	35	79.5	0.78	0.256
- No	1	2.3		
- I don't remember	8	18.2		
Would you have wanted more explanation on these risks?				
- Yes	43	97.7	0.15	0.001*
- No	1	2.3		
Did you receive an explanation about alternative options for this treatment?				
- Yes	34	72.3	0.68	0.390
- No	5	10.6		
- I don't remember	5	10.6		
To what degree did you want to be involved in the decision on the treatment?				



- The medical staff decides what is best for me	20	45.5	0.95	0.001*
- The medical staff includes me in the decision making	5	11.4		
- I get explanations and I decide what is best for me	19	43.2		
<b>To what degree did you feel involved in the decision on the present treatment?</b>				
- Too little involved	4	9.1	0.52	<0.001*
- Involved enough	32	72.7		
- Too much involved	5	18.2		
<b>How long before the treatment did you get the explanations?</b>				
- Minutes	12	27.3	0.80	0.001*
- Hours	24	54.5		
- Days	7	15.9		
- Months	1	2.3		
<b>From whom did you get most of the explanations?</b>				
- Clinic doctor	26	59.1	1.62	<0.001*
- Hospital physician	9	20.5		
- Other	9	20.5		
<b>Are you on a private medical service?</b>				
- Yes	36	81.8	0.39	0.006
- No	8	18.2		
<b>To what degree did you feel you could ask questions?</b>				
- A lot	32	72.7	0.45	0.001*
- A little	12	27.3		
<b>To what degree are you satisfied from the process of decision making for the treatment:</b>				
- Very much	16	36.4	0.60	0.002*
- Satisfied	27	61.4		
- Not at all	1	2.3		

\* Significant p value

### 9. Effects of the patients' characters on risk for invasive procedures complications:

**Table (6)** presented the effect of selected patient characters on invasive procedures complications level. There was a statistical significant effect of both gender ( $t=-17.091$ ,  $P<0.001^*$ , CI 95% = -1.00 to -0.794), age ( $t=6.228$ ,  $P<0.001^*$ , CI 95% = 0.47 to 0.92), operative status ( $t=17.09$ ,  $P<0.001^*$ , CI 95% = 0.85 to 1.08), admission status ( $t=3.09$ ,  $P=0.004^*$ , CI 95% = 0.126 to 0.173), and comorbidities ( $t=3.365$ ,  $P=0.002^*$ , CI 95% = 0.60 to 2.40) with the risk of invasive procedures complications. While ICU admission days ( $t= -0.387$ ,  $P=0.681$ , CI 95% = -0.32 to -0.14) showed non-statistically difference with the risk of invasive procedures complications. For the respondents the human error causing complications ( $t=13.735$ ,  $P<0.001^*$ , CI 95% = 2.509 to 3.373), years of experience ( $t=6.674$ ,  $P<0.001^*$ , CI 95% = 0.575 to 1.073) and general information of the respondents about invasive procedures ( $t= -4.651$ ,  $P<0.001^*$ , CI 95% = -0.574 to -0.226) showed statistical significant with the risk of invasive procedures complications.

**Table 6.** Effects of the patients' characteristic and respondents experience on the risk for invasive procedures complications (N=44).

	SE	t value	P value	CI (95%)
- Patient gender	0.112	-17.091	<0.001*	-1.00 to -0.794
- Patient age	0.112	6.228	<0.001*	0.47 to 0.92
- Operative status	0.507	17.09	<0.001*	0.85 to 1.08
- Admission status	0.500	3.09	0.004*	0.126 to 0.173
- ICU days of admission	0.115	-0.387	0.681	-0.32 to -0.14
- Comorbidities	0.446	3.365	0.002*	0.60 to 2.40
- Human error causing complications	0.214	13.735	<0.001*	2.509 to 3.373
- Years of experience	0.123	6.674	<0.001*	0.575 to 1.073

<b>- General information about invasive procedures</b>	0.086	-4.651	<0.001*	-0.574 to -0.226
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\* Significant p value

Statistical analysis is used to assess the correlation between each question and the patients' gender, when p-value is less than 0.05 means there is significant association between the questions and the patients' gender.

## Discussion

The ICUs are a significant part of the healthcare setting, and they are home to critically ill patients whose presence, along with the presence of monitors, ventilators, and other high-tech equipment, as well as a large number of staff members and the involvement of consultants from a wide range of specialties, creates unique stresses for the patients, their loved ones, and the staff. Patients who are critically sick are those who are in imminent danger of dying and hence need round-the-clock care from medical professionals and often rely heavily on medical equipment [1, 5].

Invasive procedure complications are a major cause for concern in intensive care settings since they extend patients' time in the hospital and increase their risk of dying. Improving quality and patient safety necessitates addressing the challenge of quantifying adverse events, characterizing patients, and identifying risk factors for harm from care. To intervene in the care process and build a commitment to safety at all levels of the health organization, we stress the importance of strengthening safety culture. While it's generally agreed that it's a good idea to ask for people's permission before doing anything, differing practices, subjects, and situations might pose challenges to making this a reality [6]. A cross-sectional survey of doctors and patients undergoing surgery or other invasive procedures in hospitals was conducted for this study.

The present study was applied on the following ICU doctors whom had the related demographic characteristics, 56.82% of them were male, and 95.45% of them their age was more than 30 years and 63.64% of them had 5-10 years' experience. The increase in the experience years will have a positive effect on their performance level which internally affects their patient care delivery system and needs support with continuing educational programs to re-enforce them.

Consistent with previous research [7], the current study found that doctors had an unusually high satisfactory knowledge level of the total practice of invasive procedure and central line insertion and maintenance. According to the study's findings, the vast majority of doctors in this region learn how to care for very ill patients. According to Alqarni et al. [8], medical professionals' familiarity with evidence-based practices for preventing urinary catheter infections was less than ideal. In addition, education programmes on its control and standard should be incorporated in the ICU [9].

Almost of patients admitted to our ICU experienced some sort of care-related complication, 84.09% of respondents had satisfactory total level of practice regarding invasive procedures. Most staff performed invasive procedures in ICU in our study were doctors with 68.2% and SD=1.769. According to some reports [10], paediatricians need to see less severe physiological dysfunction before admitting a patient to the intensive care unit. This could lead to a higher percentage of low-risk, monitored patients in PICUs who require fewer interventions and have a lower risk of problems than their adult counterparts.

Twenty percent of patients experienced adverse events, as shown by a study combining many approaches conducted in the United States (3.62 adverse events per 100 patients-day) [11]. Between 2008 and 2011, studies in Canada found that 19% and 13% of patients, respectively, experienced adverse effects (4.50 adverse events per 100 patients-day) [12].

A study conducted by Wambui [13] assessed events that might have harmed or actually harmed intensive care unit patients. Together, they found an adverse event were reported and another were discovered through clinical monitoring. It's probable that the wide range of estimated adverse events can be partially explained by differences in incident identification strategies, data extraction methods, rationales for choosing potential incidents, and incident confirmation definitions and procedures.

A longer ICU stay was typically observed if adverse events occurred. Significant correlations were found between adverse events and death rates. Damages associated with care are a major cause of

increased length of stay and mortality for patients who experienced an adverse event in intensive care, highlighting the need for action aimed at the care process and at incidence reduction. How long a patient stay in the hospital can change depending on their condition and the facilities available to them. Shorter-than-expected stays may be an indication of cost-cutting measures such the early discharge of patients or a more severe case (increased mortality in the first days/hours of treatment). Conversely, if a patient's hospital stay is substantially longer than anticipated, it may be an indication of subpar care quality due to complications brought on by subpar treatment (or adverse event presence) [14].

The average amount of time spent in the intensive care unit increased by 19 days when an adverse event occurred [15]; this is shorter than the increase in length of stay shown by another studies [16, 17] (2.4 days of ICU stay). An inverse causality may be at play between unfavourable events and length of ICU stay. In the event of an unfavourable outcome, the patient's exposure (length of stay) may be altered. Patients with milder illnesses typically require fewer days in the critical care unit, and those who pass away in the first few days of treatment typically experience no complications. Yet, patients who require extended hospitalization tend to be sicker and experience more complications. The factors should be taken into account when calculating the impact of adverse events [18]. These include the length of stay attributed to the event, the difference in length of stay between with and without AE, and the need for additional procedures or treatments.

Patients with adverse events had greater risks of dying in intensive care, and this proportion of fatalities in ICUs was similar to that shown in the Canadian study (25%; 95%CI: 19-31) [16]. There was an increased risk of death (OR = 3.09; 95%CI = 1.30-7.36) among patients who experienced two or more adverse events, according to the results of a cohort research conducted in intensive care units [19]. Research assessing the link between adverse events and hospital mortality indicated risk estimates that were greater in those studies [20].

We found that drugs, infections, and clinical processes/procedures accounted for the majority of invasive procedures complications. Most of the complications that occurred in ICUs were caused by clinical procedures or processes. Pressure ulcers topped the list, followed by vascular catheter handling injuries and ventilation equipment malfunctions. Damage from vascular catheter handling, damage from failure in ventilation handling, damage from urinary catheter handling, and damage from stomach catheter handling (10.8%) were found to be significantly lower than the 23% [11]. In a study of 1,126 adverse events in an intensive care unit, [21] it was found that 54 % were attributable to clinical processes/procedures, 25.8 % to medicine, 13.9 % to nutrition, and 5.5 % to infections.

In our study the most common type of complication patients suffered from were as follow, infections (75.0%), and the most common human error causing these complications ranged was invasive device dislodged from patient (38.6%), and procedure related (36.4%). In another study pressurized skin sores are a common problem in intensive care units, with estimates ranging from 3.3% to 19.6% [22]. The prevalence was significantly greater in Brazilian intensive care units (31% to 62.5%; 37), [23].

Hospital infections were deemed a consequence from procedures in a study done in France, where 34.7% of ICU admissions were associated with adverse outcomes connected to procedures. In another analysis, 9 % of patients were impacted by infections. Primary bloodstream infections, pneumonia, and central venous catheter-related infections were the most common forms of infections. An increase in mortality, length of stay, and hospital costs is connected with central venous catheter-related infections in particular. Sixty percent or more of all nosocomial bacteremia are linked to intravascular devices, according to some estimates [24].

In Roque investigation, arterial hypotension was the most common unwanted medication reaction. The use of antiarrhythmics, coronary vasodilators, antihypertensives, diuretics, general anaesthetics, opioid analgesics, and benzodiazepines was linked to hypotension incidents. From the antihypertensives studied, sodium nitroprusside was linked to the most cases of hypotension. The most significant causes of hypotension episodes were mistakes in measuring arterial pressure on an hourly basis and in adjusting dosages [25].

This study found that the quality of informed consent was high, both in terms of participants' familiarity with the informed consent process and the depth of information provided about the

potential dangers of the invasive surgery and the availability of other treatment choices. The goal of the informed consent procedure is to ensure that patients are aware of and comfortable with any potential downsides to a proposed course of treatment [26].

In another study about two-thirds of patients, however, wanted a bigger say in how their care was decided. The vast majority, meanwhile, had unanswered queries and were unaware of any available treatment alternatives. This result agrees with those of other research efforts. Because of this, it's possible that the autonomy problem among Saudis needs to be looked at again [27].

According to the data we gathered, the informed consent process is more likely to go smoothly if it is presented by the doctor themselves. Another study's recommendation that practitioners convey the informed consent 1 day before the day of the surgery was consistent with this finding [28]. The heightened anxiety of patients undergoing an invasive operation may be to blame. Having such worry suggests that the patient is in a precarious position and may be open to any form of assistance. This perspective may imply that doctors should play it safe while discussing potential dangers. Ethicists in the medical field have advocated tailoring the informed consent process to each individual [29].

The border between ethical and unethical behavior is often blurry in Western-based ethics, where autonomy is considered paramount. Patients' autonomy is sometimes less of a priority in societies where a desperate need for medical care ranks higher [30].

One surprising finding from the current study was that over half of the patients believed that the medical staff decides what is best for them and the other got explanations and decided what is best for them. Another Pakistani survey showed the same thing, with 56% of participants reporting this view, therefore these results are consistent. This finding raises the question of whether the patient's acquiescence was motivated by fear and submission or by the physician's paternalistic tactics. This finding of a paternalistic culture may have been influenced by the fact that the majority of the participants in their study were females [31].

Although it is crucial to take into account and honor the beliefs of other cultures, this should not be done at the expense of individuals' basic rights. Most of the patients received an explanation about the risks from the treatment with and received an explanation about alternative options for the treatment. Majority of the patients felt that they were involved enough in the decision on their treatment and felt free to ask questions and also felt satisfied from the process of decision making for the treatment. One possible explanation for this result is that patients' evaluations are influenced by the prestige associated with receiving free medical care in a tertiary care hospital. When asked about the informed consent process, patients had positive reactions. The vast majority of patients who gave their consent expressed happiness.

## **Conclusion**

Knowledge, procedural application, and invasive procedure performance were shown to be positively correlated following the delivery of the simulated education program, and years of experience as indicated by the results of the current study. Also the findings of this study show that either patients in trapoli are aware of their rights or that physician paternalism is prevalent in the country. Apparently, more study is needed to improve the quality of informed consent. The highest standard was reached when doctors themselves were in charge of the explanation. The findings of this study suggest that critical care staff' theoretical and practical understanding of invasive operations, as well as their performance in these areas, might all benefit from improvement.

## **Recommendations**

Based on the study findings it is recommended that

- ✓ Intensive care unit staff participate in an orientation and periodic in-service training programme to improve their skills in performing invasive operations.
- ✓ Building a streamlined, all-inclusive pamphlet with instructions for ICU staff to follow when carrying out invasive treatments.
- ✓ Recommendations for routine practice: Have hospitals institutionalize the use of guidelines for the safe and effective execution of invasive procedures in the emergency and critical care settings.

- ✓ Identifying the needs of staff in terms of their performance during invasive procedures in the intensive care unit requires constant review of their practice.
- ✓ Health care providers, especially physicians, be educated on the significance of informed consent so that it is no longer viewed as merely routine.
- ✓ Patients be given more freedom to make their own decisions regarding their care without feeling rushed or pressured by anyone.
- ✓ Patients be given a copy of any consent forms they sign.

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