Invasive Devices: Its Effects on Occurrence of Complications and Mortality Rate among Intensive Care Patients

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Abstract:
Background: Several invasive devices are connected daily in intensive care patients. It is evident that complications associated with these invasive devices are potentially life threatening. Aim of the study: Explore the effect of invasive devices on occurrence of complications and mortality rate among intensive care patients. Research design: Prospective correlational research design. Setting: Intensive Care Units as Coronary ICU, Cardio-Thoracic SICU, Trauma ICU, Medical ICU, General ICU, Critical ICU, Neuro-stroke ICU, Neuro SICU and Gastrointestinal ICU, all at Assiut University Hospitals. Patients: Intensive care patients (160), were assigned into two groups (68 patients had one or two invasive devices and 92 patients had three or more invasive devices). Tools: Adult critically ill patient assessment tool and patient outcome assessment tool. Results: Critically ill patients who had many invasive devices were exposed to higher complications and mortality rate (89.1% & 55.4% versus 14.7% & 2.9%) in those who have few invasive devices, respectively. Conclusions: Increased number of invasive devices was linked to a greater mortality rate and a higher incidence of complications. Recommendations: Continuously reducing number and also following care bundles for insertion, maintaining and removal of all invasive devices connected with intensive care patients.

Keywords: Invasive device, Intensive care patients, Mortality rate & Complications.

Introduction:
The idea of medical invasiveness stems from the fact that certain patients have devices that pierce their bodies through their skin or other orifices. The utilization of medical invasive devices in an intensive care unit (ICU) aims to enhance patient care through condition monitoring and drug administration in accordance with established guidelines (World Health Organization, 2022).

The most common support and monitoring invasive devices used in the ICU include intravenous catheters either centrally and peripherally, nasogastric tube, endotracheal tube, hemodialysis double-lumen catheter and chest tube, whereas the less common used devices as tracheostomy tube, nephrostomy tube, wound drains or gastrostomy tube. The diseases severity and complexity of the critically ill patients determine the need for performed invasive procedures. Therefore, advanced monitoring techniques are needed to prevent physiologic deterioration, while the underlying disease treated and resolved (Perel et al, 2016 &Thimmapur et al, 2018).

Despite benefits related to invasive devices, it is associated with many side-effects such as device-associated healthcare-acquired infections, which constitute one of the biggest risks to patient safety. They are also a major cause of patient morbidity and mortality. There have been reports of mortality rates ranging from 20.5 to 60.4% in various intensive care units in our nation (ÇAKIR et al., 2020).

Healthcare hazards and threats to patient safety are primarily attributed to infectious complications, such as catheter-related urinary tract infections, central-line-associated bloodstream infections, and ventilator-associated pneumonia. The most frequent non-infectious side effects are bleeding, air embolism, thoracic duct damage, arterial puncture, hypoxemia, hemotoma and pneumothorax, haemothorax and arrhythmia (Van et al., 2021).

Significance of the study:
Patients in the intensive care units, increasingly receive invasive medical devices, which are associated with increased risk for health care–associated infections (HAIS). These infections prolong ICU and hospital stays, raise mortality risk, cause adverse effects, increase antibiotic consumption and inflate the costs of care (Blot et al., 2022 & Branson & Rodriguez., 2023). It has been found that approximately (6328) patients admitted annually to intensive care units at assiut university hospitals, that highest of these patients have HAIs. Therefore, the current study, focus on correlation between the effect
of number of invasive devices on outcomes among critically ill patients.

**Aim of the study:**
To explore the effect of invasive devices on occurrence of complications and mortality rate among intensive care patients.

**Research questions:**
Q1. What is the effect of invasive devices on occurrence of complications and mortality rate among intensive care patients?

**Patient and Method:**

**Research design:**
Prospective correlational research design was utilized in the current study.

**Study variables:**
- Independent variables "number of invasive devices"
- Dependent variables " occurrence of complications and mortality rate"

**Setting of the study:**
The data was collected from different intensive care units (Coronary ICU, Cardio-Thoracic SICU, Trauma ICU, Medical ICU, General ICU, Critical ICU, Neuro-stroke ICU, Neuro SICU and Gastrointestinal ICU), all at Assiut University Hospitals, in Egypt. This setting was selected because patients in ICU need more advanced monitoring invasive devices.

**Sample:**
The available study participants consisted of all intensive care patients, during period of six months (who were 160 patients). These patients were divided into one or two invasive devices (group 1 = 68 patients) and three or more invasive devices (group 2 = 92 patients).

**Recruitment:**
A consecutive sampling model was used where all patients admitted to ICU who meet the eligibility criteria were invited to participate. Patients meeting study criteria were identified within 24 hours of admission.

**Inclusion criteria:**
1- Newly admitted intensive care patients within 48 hours ago, who received invasive connections.
2- Patient's age between 18 – 65 years.

**Exclusion criteria:**
1- Diabetic patient.
2- Patient with human immunodeficiency virus.
3- Patient with immunosuppressive therapy.

**Data Collection Tools:**

**Tool (I): Intensive care patient assessment tool:**
This tool was developed by researcher after review of literatures (Mohamed et al., 2018 & Melaku et al., 2024), to form the baseline data. This tool consists of three parts as following:

Part (1): Patient's personal characteristics: It included patient's code, gender, age, and smoking.
Part (2): Medical data: This part included history of past medical and surgical problems, causes of ICU admission and diagnosis.
Part (3): Invasive device assessment sheet: This part involves type of invasive device as endotracheal tube, tracheostomy, central venous catheter, urinary catheter or other which inserted within patient's body, date of insertion, start date from admission date of extraction, duration and number.

**Tool (II): Patient outcome assessment tool:**
This tool was developed by the researcher after reviewing the relevant literature (Mohamed et al., 2023 & Melaku et al., 2024). This tool used to assess incidence of complications with its type and mortality rate, which included two parts as following:

Part (1): Occurrence of complications:
Assessment of complications related to invasive devices such as peripheral and central venous catheters may cause air embolism, fever and blood stream infections, endotracheal and tracheostomy tubes may cause pneumothorax, haemothorax, and ventilator associated pneumonia, urinary catheters cause haematuria and catheter associated urinary tract infection, and nasogastric tube which cause fever, sinusitis aspiration and pneumothorax, which was done from insertion of the invasive devices until extraction on a periodic manner.
Part (2): Mortality: This section determined either patient dead or survived at discharge from intensive care unit, rating from (0) mean that patient's dead and (1) mean that patient's survived.

**Methods:**

**Preparatory phase:**
- Construction for data collection tools was done by the researcher after extensive literature review.
- An official permission to carry out the study will be obtained from the Assiut university hospital responsible authorities in stroke, coronary, anesthesia, neuro- surgical, general, trauma, cardio-thoracic surgical, gastrointestinal and medical intensive care units after explaining the aim and nature of the study.

**Validity of study tools:**
The material of tools was designed and validated for content validity by jury of (4) experts who are specialists in field of critical care and emergency nursing and by (3) experts who are specialists in anesthesia and intensive care medicine department and necessary modifications were done.

**Reliability of study tools:**
The reliability of the test was calculated for: "Tool one "Adult intensive care patient assessment tool was accepted with percentage 88%." Tool two" Clinical
outcome assessment tool by using correlation coefficient was accepted with percentage 90%. It was estimated by Alpha Cronbach’s test for this study.

A pilot study:
A pilot study of (10%) patients was conducted in the selected setting to examine the applicability, feasibility, efficiency and the clarity of the developed tools, before beginning of data collection.

Ethical consideration:
The research proposal received approval from the Ethical Committee at the Faculty of Nursing – Assiut University. There were no risks identified for the participants during the research process. Patients were informed about their right to discontinue their participation in the study at any time. The study adhered to standard ethical principles in clinical research, ensuring both confidentiality and anonymity for all patients (1120240633).

Implementation phase:
• The data collection conducted in intensive care units at Assiut university hospitals during period of six months started from September 2023, end at February 2024.
  ▪ The researcher started to collect data from patients' admission until discharge.
  ▪ The researcher collected data about patient's personal characteristics, medical data, type of invasive device, duration and number.
  ▪ The researcher assessed each patient to collect data about effect of invasive devices on his/her outcomes as incidence of complications and mortality.

Statistical design:
The statistical package for IBM SPSS version (26) software was used to analyze data. Descriptive statistics (frequencies and percentages, mean and standard deviation, Pearson correlation coefficients, independent sample T – test, Chi – square i.e.) were done by using computer program (SPSS) for quantitative and qualitative data to determine significance. The critical value of the tests “P” was considered statistically significant when P – value less than (0.05).

Results:

Table (1): Distribution of personal characteristics and medical data among patients, total number = 160

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Invasive devices groups</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One or two (group 1 = 68)</td>
<td>Three or more (group 2 = 92)</td>
</tr>
<tr>
<td>Age (Mean ± SD)</td>
<td>(44.35 ± 15.23)</td>
<td>(41.84 ± 15.61)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>34 (50.0%)</td>
<td>71 (77.2%)</td>
</tr>
<tr>
<td>Female</td>
<td>34 (50.0%)</td>
<td>21 (22.8%)</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25 (36.8%)</td>
<td>57 (62.0%)</td>
</tr>
<tr>
<td>No</td>
<td>43 (63.2%)</td>
<td>35 (38.0%)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory problems</td>
<td>5 (7.4%)</td>
<td>6 (6.5%)</td>
</tr>
<tr>
<td>Cardiovascular problems</td>
<td>19 (27.9%)</td>
<td>11 (12.0%)</td>
</tr>
<tr>
<td>Neurological problems</td>
<td>8 (11.8%)</td>
<td>12 (13.0%)</td>
</tr>
<tr>
<td>Gastrointestinal problems</td>
<td>5 (7.4%)</td>
<td>12 (13.0%)</td>
</tr>
<tr>
<td>Hepatic problems</td>
<td>3 (4.4%)</td>
<td>2 (2.2%)</td>
</tr>
<tr>
<td>Metabolic problems</td>
<td>12 (17.6%)</td>
<td>10 (10.9%)</td>
</tr>
<tr>
<td>Organ failure</td>
<td>6 (8.8%)</td>
<td>2 (2.2%)</td>
</tr>
<tr>
<td>Poisoning</td>
<td>3 (4.4%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Trauma</td>
<td>7 (10.3%)</td>
<td>37 (40.1%)</td>
</tr>
</tbody>
</table>

* Statistically significant difference (P-Value < 0.05).

Independent-Samples T Test for (Mean ± SD)
Chi-Square Test for (Number and percentage).
Table (2): Distribution of patients, as regarding to type of invasive device and its duration of connection, n = 160

<table>
<thead>
<tr>
<th>Invasive device type</th>
<th>Invasive devices groups</th>
<th>P-Value</th>
<th>Invasive devices groups</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One or two (group 1 = 68)</td>
<td></td>
<td>Three or more (group 2 = 92)</td>
<td></td>
</tr>
<tr>
<td>Peripheral venous catheter</td>
<td>Yes (No. %)</td>
<td>63 (92.6%)</td>
<td>57 (62.0%)</td>
<td>.001*</td>
</tr>
<tr>
<td></td>
<td>Duration (Mean ± SD)</td>
<td>5.76 ± 2.80</td>
<td>7.53 ± 5.02</td>
<td>.001*</td>
</tr>
<tr>
<td>Central venous catheter</td>
<td>Yes (No. %)</td>
<td>8 (11.8%)</td>
<td>61 (66.3%)</td>
<td>.001*</td>
</tr>
<tr>
<td></td>
<td>Duration (Mean ± SD)</td>
<td>7.38 ± 3.46</td>
<td>16.20 ± 11.46</td>
<td>.064</td>
</tr>
<tr>
<td>Urinary catheter</td>
<td>Yes (No. %)</td>
<td>42 (61.8%)</td>
<td>92 (100.0%)</td>
<td>.001*</td>
</tr>
<tr>
<td></td>
<td>Duration (Mean ± SD)</td>
<td>6.45 ± 2.88</td>
<td>15.08 ± 10.61</td>
<td>.001*</td>
</tr>
<tr>
<td>Nasogastric tube</td>
<td>Yes (No. %)</td>
<td>2 (2.9%)</td>
<td>70 (76.1%)</td>
<td>.001*</td>
</tr>
<tr>
<td></td>
<td>Duration (Mean ± SD)</td>
<td>5.00 ± .00</td>
<td>14.86 ± 11.91</td>
<td>.152</td>
</tr>
<tr>
<td>Endotracheal tube</td>
<td>Yes (No. %)</td>
<td>0 (0.0%)</td>
<td>58 (63.0%)</td>
<td>.001*</td>
</tr>
<tr>
<td></td>
<td>Duration (Mean ± SD)</td>
<td>-</td>
<td>8.15 ± 3.64</td>
<td>-</td>
</tr>
<tr>
<td>Tracheostomy</td>
<td>Yes (No. %)</td>
<td>0 (0.0%)</td>
<td>18 (19.6%)</td>
<td>.001*</td>
</tr>
<tr>
<td></td>
<td>Duration (Mean ± SD)</td>
<td>-</td>
<td>23.06 ± 12.60</td>
<td>-</td>
</tr>
<tr>
<td>Drain</td>
<td>Yes (No. %)</td>
<td>35 (38.1%)</td>
<td>35 (38.1%)</td>
<td>.001*</td>
</tr>
<tr>
<td></td>
<td>Duration (Mean ± SD)</td>
<td>8.00 ± .00</td>
<td>11.82 ± 14.15</td>
<td>.250</td>
</tr>
</tbody>
</table>

Independent-Samples T Test for (Mean ± SD)
* Statistically significant difference (P-Value < 0.05).

Chi-Square Test for (Number and percentage).

Table (3): Frequency and percentage of occurrence of complications among patients as regarding to invasive devices groups, n = 160

<table>
<thead>
<tr>
<th>Occurrence of complications</th>
<th>Invasive devices groups</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One or two (group 1 = 68)</td>
<td></td>
</tr>
<tr>
<td>Hospital acquired infection</td>
<td>(No. %)</td>
<td>7 (10.3%)</td>
</tr>
<tr>
<td>Fever</td>
<td>(No. %)</td>
<td>3 (4.4%)</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>(No. %)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Air embolism</td>
<td>(No. %)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Absence of complications</td>
<td>(No. %)</td>
<td>58 (85.3%)</td>
</tr>
</tbody>
</table>

Chi-Square Test for (number and percentage)
* Statistically significant difference (P-Value < 0.05).

Figure (1): Percentage distribution of mortality rate among patients according to invasive devices groups (n = 160)
Table (1): The results revealed that the mean and SD of age was 44.35 ± 15.23, and 41.84 ± 15.61 in the group 1 and group 2, respectively. Regarding to gender, showed that 77.2% of studied patients were male, in group 2, (P = .001*). Concerning to smoking status, the results demonstrated that 62.0% of patients in group 2 were smokers, (P = 0.002*). Pertaining to diagnosis, the results demonstrated that the most common diagnosis in group 1 was cardiovascular problems 27.9%, while trauma in group 2 was 40.1%, (P = .001*).

Table (2): Announced that the most common invasive devices were PVCs, CVCs, UCs, NGTs and ETTs. The results revealed that PVCs was more connected with patients in group 1 92.6%, with mean and SD of duration of connection 5.76 ± 2.80. While, CVCs, UCs, NGTs and ETTs were more connected with patients in group 2 66.3%, 100%, 76.1% and 63.1% with mean and SD of duration of connection 16.20 ± 11.46, 15.08 ± 10.61, 14.86 ± 11.91 & 8.15 ± 3.64.

Table (3): Showed that most common infectious complication was hospital acquired infection 80.4% in group 2. While 85.3% of patients were free of complications in group 1, (P = .001*).

Figure (1): Demonstrated that 55.4% of patients in group 2 were dead, compared with 97.1% of patients in group 1 were survived, (P = .001*).

Discussion:
The complications and outcomes associated with invasive devices among critically ill patients may arise at the time of the insertion, or may develop after the device has been in place for some time, which include health care associated infection and sepsis, prolonged length of stay, fever, haemothorax, pneumothorax, death or other (Pronovost, et al., 2021). Therefore, this study aimed to provide insight in the association between number of invasive devices with occurrence of complications and mortality rate among intensive care patients:

In relation to gender, the present study showed that majority of patients were males, mainly presented in the three or more invasive devices group. This could be attributed by fact that males are more susceptible to higher risks of accidents, trauma, and injuries, as well as respiratory diseases resulting from smoking. These findings were consistent with a previous study conducted by De Macedo et al., (2022), who showed that males being admitted to the intensive care units are more than female patients.

Concerning to the smoking status, the present study announced that more than half of patients in three or more invasive devices group were smokers, compared with more than half of patients in one or two invasive devices group were non-smokers. Due to detrimental effects of smoking on health, including an increased risk of cancer, heart disease, stroke, lung diseases, diabetes, and chronic obstructive pulmonary disease, it can be inferred that smoker patients admitted to intensive care units are more likely to require multiple invasive medical devices. This finding was supported with the study by Shrestha et al., (2022), which presented a significant correlation between studied groups who have hospital acquired infections and others who don’t have, and attributed these infections to the use of many invasive devices in relation to smoking status.

Regarding to diagnosis of the studied patients, the present study illustrated that the most common diagnosis in one or two invasive devices group was cardiovascular problems, while it was trauma in three or more invasive devices group. This may be attributed to the fact that the hemodynamic status as well as severity of conditions are worse in patients with trauma than those with cardiovascular problems. This finding comes in line with study done by Mohamed et al., (2018), who showed that trauma is first leading cause of admission and this may be due to high percentage of road traffic accident, followed by respiratory and cardiovascular problems with statistically significant difference among studied groups regarding diagnosis.

Pertaining to types of invasive devices, the current investigation revealed that the most frequently used invasive support and monitoring devices in the intensive care unit were peripheral venous catheters, central venous catheters, urinary catheters, nasogastric tubes and endotracheal tubes. Furthermore, peripheral venous catheter used commonly with two or with three or more invasive devices, whereas central venous catheters, urinary catheters, nasogastric tubes and endotracheal tubes used mainly with three or more invasive devices. This is similar with Takashima et al., (2024) study, which illustrated those intravenous catheters both centrally and peripherally, nasogastric tubes and endotracheal tubes are the most frequently used invasive support and monitoring devices in the intensive care unit.

Concerning duration of connection for the invasive devices, this study revealed that duration of all invasive devices was significantly longer in patients who had three or more invasive devices than those with one or two invasive devices. This can be attributed by fact that patients who require continuous and intensive monitoring of their vital signs upon admission are more likely to have a higher number of invasive devices. Furthermore, the incidence of catheter associated infection increased, leading to prolongation of the duration for all invasive devices. The present study agreed with Bennett et al., (2018) & De Macedo et al., (2022) study, which showed
significantly longer duration of all invasive devices among patients who developed health care associated infections.

Regarding occurrence of complications among patients, the findings revealed highly statistically significant association between a decrease in the number of invasive devices and the absence of complications, when comparing different groups of invasive devices. The study also reported that HAIS were the most common infectious complications observed. This can be attributed to severity and complexity of the patients’ illnesses, which necessitate implantation of multiple invasive devices. This increases the likelihood of microbial entry due to non-aseptic techniques during device insertion and care, as well as the risk of injury. These findings align with the study conducted by Van et al., (2021 & Takashima et al., 2024), which highlighted the healthcare hazards and threats to patient safety associated with the insertion of invasive lines. The most frequent complications were found to be infectious, such as HAIS.

Regarding to mortality, the current study demonstrated that incidence of mortality in group of patients with three or more invasive devices was more than in group of patients with one or two invasive devices with highly statistically significant difference. This can be attributed by fact that intensive care patients often require the use of multiple invasive devices and supportive equipment. These devices can pose a risk of device-associated healthcare-acquired infections (DA-HAIs), which are a significant threat to patient safety. DA-HAIs can lead to complications such as bacteremia, sepsis, and septic shock, which are major causes of patient morbidity and increased mortality. These findings are supported by the study conducted by Júnior et al., (2023 & Melaku et al., 2024), which revealed that all invasive devices connected to intensive care patients were associated with an elevated risk of HAIS. These infections were identified as risk factors for increased mortality among patients.

Conclusion:
It can be concluded that there was highly statistically significant difference between number of invasive devices with occurrence of complications and mortality rate among intensive care patients.

Recommendation:
Based on findings of the present study, the best recommendations include the following:

- Follow care bundles for insertion of the invasive devices.
- Used aseptic technique and excellent care when dealing with invasive devices.
- Reassess the need for all invasive connections and continuously try to reduce their number.

References:
- Perel, A., Saugel, B., Teboul, J., Malbrain, M., Belda, F., Fernández-Mondéjar, E., &


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