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EFFECT OF INTERVENTION PROTOCOL ON NURSING-SENSITIVE OUTCOMES OF PATIENTS WITH EPIDURAL ANALGESIA

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ABSTRACT

Background: Epidural analgesia insertion is common technique used to manage acute and chronic pain for patients with cancer, after major surgery, and is viewed as the 'gold standard for effective management. Nursing management is essential for long term epidural analgesia to reduce the risk of complications. **Aim:** This study aimed to evaluate the effect of intervention protocol on nursing sensitive outcomes of patients with epidural analgesia. **Design:** Quasi experimental research (study &control) design was used to achieve the aim of this study. **Setting:** This study was conducted at Surgical Intensive Care Unit (SICU) at National Cancer Institute (NCI) affiliated to Cairo University. **Subject:** A purposive sample consists of 100 adult patients. **Tools:** (I) Nursing-Sensitive Outcomes Assessment Scale. It was composed of three parts. Patient demographic data, Patients medical data and Nursing- Sensitive Patients Outcomes scales to assess patient's outcomes after epidural analgesia. **Results:** there was lower total mean score of physiological and psychological health outcomes among study group ~~of~~ patients rather than total mean score of control group ~~of~~ patients. There was high total mean score of health knowledge outcomes among study group of patients than total mean score of control group of patients **Conclusion**: this study concluded that there was a significant improvement on patients' nursing sensitive outcomes post implementation of intervention protocol. The implementation of intervention protocol for patients with epidural analgesia has a statistically significant positive effect on their physiological, psychological and health knowledge outcomes which support the stated hypothesis. **Recommendations:** Replication of the current study on larger probability sample is recommended to achieve generalization of the results.

Key words: epidural analgesia, nursing sensitive patients outcomes

INTRODUCTION

Epidural anesthesia is a technique for perioperative pain management with multiple applications in anesthesiology. It is useful as a primary anesthetic, but most commonly, it is used as a pain management adjuvant. It can be a single shot or a continuous infusion for long-term pain relief. Aside from the benefit of potentially providing excellent analgesia, its use reduces the exposure to other anesthetics and analgesics, decreasing side effects. It has also shown to decrease cortisol levels, expedite the return of bowel function, decrease the incidence of pulmonary embolism and deep venous thrombosis (DVT) in the postoperative period, and shorten lengths of in-hospital stay **(Hernandez& Singh, 2022).**

The epidural technique is one of the earliest ones in the field of anesthesia. Properly performed, it is a safe technique that provides multiple benefits. It is usable as a sole anesthetic for surgical

procedures, decreasing the need for general anesthesia and airway management, with the risks that this implies. It also reduces the exposure to volatile anesthetics and may potentially decrease the opioid requirement during or after a procedure, lowering the incidence of the side effects associated with these drugs. The epidural technique is also highly valuable for postoperative pain management as part of a multimodal approach **(Toledano & Van de Velde, 2017).**

In addition to provide analgesia in the intraoperative, postoperative and end-of-life settings; and can be used as the primary anesthetic for surgeries from the mediastinum to the lower extremities. In addition, epidural techniques are used increasingly for diagnostic procedures, acute pain therapy, and management of chronic pain. Epidural block may also reduce the surgical stress response, the incidence of perioperative thromboembolic events, and, possibly, the morbidity and mortality associated with major surgery **(Hernandez& Singh, 2022).**

Epidural analgesia is the administration of opioids and/or local anesthetics into the epidural space. It can be used to manage pain in pediatric, adult, and older adult patients on a short-term (hours to days) or long-term (weeks to months) basis. Short-term epidural analgesia is achieved by inserting a needle in the epidural space and injecting analgesics, or by threading a catheter through the needle and using it to administer analgesics. It's used to manage postoperative pain, procedural pain, trauma pain, or labor pain **(Toledano & Van de Velde2017).**

Significance of the study:

According to National Cancer Institute statistics (2021) about 300 epidural catheters were inserted into patients in this year **(National Cancer Institute, Egypte, 2021).** Although EA is generally considered safe, serious complications including spinal hematoma and abscess can occur, potentially leading to irreversible neurological deficit. According to **Marta et al. (2021)** study, the incidence of complications related to epidural analgesia was from 10,838 patients referred to acute pain unit, 1093(10.1%) had side effects or complications. Incidence of sensory (48.5%) or motor deficits (11.8%), nausea or vomiting (17.5%) and pruritus (8.0%); The least common complications: 3 (0.03%) subcutaneous epidural hematoma, 3 (0.03%) epidural abscesses.

From clinical observation in the intensive care units, it has been observed that large number of patients receiving epidural analgesia through epidural catheter developed many complications such as epidural hematoma, epidural abscess, and epidural site infection. These complications may have negative impact on the patients' physical and psychological condition and consequently prolong hospital stay and increase hospital cost. Therefore, this study will be conducted in an attempt to explore the effect of intervention protocol on nursing sensitive outcomes of patients with epidural analgesia.

AIM OF THE STUDY

This study aimed evaluate the effect of intervention protocol on nursing sensitive outcomes of patients with epidural analgesia through the following: -

- Assessing nursing-sensitive outcomes regarding epidural analgesia pre intervention protocol implementation.
- Applying nursing intervention protocol regarding epidural analgesia.
- Evaluating the effect of nursing intervention protocol on nursing-sensitive outcomes of patient with epidural analgesia.

Research hypotheses:

the current study hypotheised that

The interventions protocol will improve the nursing-sensitive outcomes of patients with epidural analgesia as compared to control group.

Operational definition of nursing intervention protocol: assess physiological, phsycological and health knowledge outcome post care of epidural analgesia.

SUBJECTS AND METHODS

- **Research design:**

Quasi experimental research (study & control) design was used to achieve the aim of the present study. Quasi-experimental design is the implementation and testing of an intervention in the absence of randomization (Denise & Cheryl Tatano, 2018).

- **Setting:**

The study was conducted at Surgical Intensive Care Units at National Cancer Institute affiliated to Cairo University.

- **Subjects:**

A purposive sample were recruited in this study from the previous mentioned setting who agreed to participate in this study. Based on retrospective statistical data, it was found that the number of patients who had an epidural catheter for pain management in intensive care unit at national cancer institute in (2021) were 300 patients.

A purposive sample were consisting of (100) adult patients connected with epidural catheter.

Inclusion criteria:

Adult patients, from both genders, connected with epidural catheter, conscious, free from any neurological disease, spinal cord injury, or any disease affect motor and sensory functions were recruited for this study.

Tools for data collection:

The following tools were used for data collections:

I - Patients Assessment Record:

This tool was developed by the researcher in English language after reviewing the current national and international related literatures and it included the following:

Part (1): Patients' demographic characteristics: This part used to assess patients' demographic data, it was consisted of 7 items such as patients' age, gender, marital status, level of education, work status, nature of work, ~~social status~~ and residence.

Part 2: General Medical Data: It was concerned with assessment of patients' medical health and it consisted of 6 question such as (smoking, types of smoking, ~~no of cigarette per day~~, weight, height and body mass index).

Part 2: Past Medical History: It was concerned with assessment of patients' past medical history and it consisted of one MCQ question about comorbid disease such as (diabetes mellitus, Hypertension, Ischemic heart disease and others).

~~Part 4:~~ Past surgical history: ~~It was concerned with assessment of patients' past surgical history it was consisted of two question~~ about previous epidural catheter insertion or cranium or spine surgery).

III- Nursing- Sensitive Patients Outcomes scales: This tool was adapted from Marions johnsn & Merdian mass, 2000) to assess nursing sensitive patient outcomes for patients with epidural analgesia. It included three domains as follows:

First Domain: Physiological health outcomes:

This domain describes 11 physiologic and physical functioning of the patients with epidural analgesia that include the following -outcomes: [respiratory status & gas exchange Cardiac pump effectiveness peripheral tissue perfusion, circulation status, vital signs status, pain level, motor and sensory deficit (epidural abscess or hematoma), urinary elimination, vomiting & nausea, risk for injury and infection].

Scoring system: -

This domain consisted of 93 indicators, each outcome was scaled differently and based on ranges, these ranges mentioned in the tool These ranges based on literature review as follows:

1) Respiratory status and gas exchange adopted from (Walsh, et al.,2013; Elliott & Coventry, 2012; Alexis, 2010). It was consisted of 11 indicators as follow (Mental status IER, Ease of breathing, Dyspnea at rest, Dyspnea with exertion, Restlessness not present, Cyanosis not present, Somnolence- not present, Pao2 WNL (80-100), Pco2 WNL (35-45), Arterial pH WNL (7.35-7.45), Oxygen saturation WNL (95-100)

Total score was 11, it was categorized as follows:

- 11 →not compromised.
- >11-22→moderately compromised.
- >22-33 →severely compromised.

2) Cardiac pump effectiveness adopted from (American Heart Association,2018 & Schroth, 2015) it was consisted of 7 indicators as follow (Heart rate IER, Activity tolerance, Dysrhythmia not present, Chest pain not present, Dyspnea at rest, Dyspnea with exertion, Central Venous Pressure (CVP) (5-10)mmhg)

Total score was 21, it was categorized as follows:

- 7 →not compromised.
- >7-14 →moderately compromised.
- >14-21 →severely compromised.

3) Tissue perfusion: peripheral adopted from (Moorhead, Johnson, Maas &Swanson, 2014). It was consisted of 4 indicators as follow (Capillary refill brisk, Distal peripheral pulses strong, Skin color normal, Peripheral edema not present)

Total score was 12, it was categorized as follows:

- 4→ not compromised.
- >4-8→moderately compromised.
- >8-12→severely compromised.

4) Circulation status adopted from (Rieser, 2013; Burchell & Powers, 2011) It was consisted of 4 indicators as follow (Orthostatic hypotension not present, Extreme fatigue not present, Extremity temperature warm).

Total score was 9, it was categorized as follows:

- 3 → not compromised.
- >3-6 →moderately compromised.
- >6-9 →sever compromised.

5) Vital signs status adopted from (Walsh, et al.,2013; Elliott & Coventry, 2012; Alexis, 2010). It was consisted of 4 indicators as follow (Temperature, Radial pulse rate, Respiratory rate, Blood pressure).

Total score was 12, it was categorized as follows:

- 4→ not compromised.
- >4-8→moderately compromised.
- >8-12→severely compromised.

5) Pain control adopted from (Moorhead, et al., 2014). It was consisted of 14 indicators as follow (1-Reported pain (NRS), Percent of body affected, Frequency of pain, Length of pain episodes, Oral expression of pain, Facial expression of pain, Protective body position, Restlessness, Muscle tension, Change in respiratory rate, Change in heart rate, Change in BP, Perspiration, Appetite loss).

Total score was 42, it was categorized as follows:

- 14 → not compromised.
- >14-28→moderately compromised.
- >28- 42→severely compromised.

6) spinal sensory and motor function (Moorhead, et al., 2014). It was consisted of 7 indicators as follow (Head and shoulder movement, Autonomic functions, Deep tendon reflexes, Body skin sensation, Strength of extremity movement, Flaccidity not present, Pronator drift not present).

Total score was 21, it was categorized as follows:

- 7 → not compromised.
- >7-14→moderately compromised.
- >14-21→severely compromised.

7) Urinary Elimination (Moorhead, et al., 2014) it was consisted of 13 indicators as follow (Elimination pattern IER, Urine odor IER, Urine amount IER, Urine color IER, Urine clarity, Digestion of adequate fluid, 24 hours intake and output balanced, Urine passes without pain, Urine passes without urgency, Urinary continence, Empties bladder completely, Urinary retention, Recognition of urge)

Total score was 39, it was categorized as follows:

- 13→ not compromised.
- >13-26→moderately compromised.
- >26-39→severely compromised.

7) nausea and vomiting it was consisted of 10 indicators as follow (Eating pattern IER, Oral intake WNL, Abdominal pain, Abdominal sound WNL, Appetite change, Feeling of nausea, Emesis, Number of emesis, Amount of emesis, Color of emesis)

Total score was 30, it was categorized as follows:

- 10 → not compromised.
- >10-20→moderately compromised.
- >20-30→severely compromised.

8) risk for injury it was consisted of 6 indicators as follow (Skin bruises, Catheter shearing, Accidental removal of epidural catheter, Wrong drug administration, Epidural catheter disconnection, Impaired mobility)

Total score was 18, it was categorized as follows:

- 6 → not compromised.
- >6-12→moderately compromised.
- >12-18→severely compromised.

9) risk for infection it was consisted of 14 indicators as follow (Rash, Uncrusted vesicles, Foul smelling discharge, Purulent sputum, Purulent drainage, Pyuria, Fever, Pain/ tenderness, Malaise, Chilling, Wound site healing, Wound site culture colonization, WBC elevation, WBC depression)

Total score was 42, it was categorized as follows:

- 14 → not compromised.
- >14-28→moderately compromised.
- >28-42→severely compromised.

-It was considered that the lower score the better physiological outcomes.

Second Domain: Psychological health Outcomes:

This domain describes psychological functioning and includes two parameters as follows:

1. Self-control that includes anxiety control it was consisted of 9 indicators as follow (Monitor intensity of anxiety, decrease environmental stimuli when anxious, Seek information to reduce anxiety, Use relaxation technique to reduce anxiety, Maintain social relationship, Maintain concentration, Report adequate sleep, Report absence of physical manifestation, Control anxiety response).
2. well-being that includes comfort level it was include 7 indicators as follow (Report physical wellbeing, report psychological wellbeing, expressed contentment with physical surroundings, expressed contentment with social relationship, expressed spiritual contentment, Report satisfaction with level of independence, Expresses satisfaction with pain control)

Scoring system: -

This domain consisted of 9 indicators; each one was scaled as follows: For identity and anxiety control, the scales were as follows:

Consistency demonstrate = 1, Sometimes demonstrate = 2, Never demonstrate = 3

Total score for anxiety control was 27, it was categorized as follows:

- 9→ not compromised.
- >9-18 →moderately compromised.
- >18-27→severely compromised.

Total score for level of comfort was 21, it was categorized as follows:

- 7→ not compromised.
- >7-14→moderately compromised.
- >14-21 →severely compromised.

The lower score the most positive outcomes.

Third domain: health knowledge outcomes: This domain describes an individual understanding and skill in applying information to promote maintain and restore health. It was categorized as follow: -

a- Health knowledge about epidural catheter it was consisted of 5 indicators as follow (Importance of epidural catheter, Indication of epidural catheter, contraindication epidural catheter, complication of epidural catheter and Nursing care of epidural catheter).
b- Health knowledge about medications given in epidural catheter it was consisted of 4 indicators as follow (Medication dose, Medication side effect, Medication precaution, Correct medication administration).
c- Health knowledge about prescribed activity for patient with epidural catheter it was consisted of 4 indicators as follow (prescribed activity, activity restriction, activity precaution, proper performance of exercise).
d- Health knowledge about signs of infection it was consisted of 2 indicators as follow (Able to identify signs and symptoms of infections and Ensure clean wound site).

Scoring system:

This domain consisted of 15 indicators; each one was scaled as follows:

Total score for level of epidural catheter care knowledge was 45, it was categorized as follows:

- 15→ never demonstrated.
- >15-30→moderately demonstrated.
- >30-45 →constantly demonstrated.

The high score the most positive outcomes.

Ethical considerations:

- The researcher clarified the objective and aim of study to the subjects included in the research study.
- A written approval was obtained from the Scientific Ethics Research Committee of the Faculty of Nursing Ain Shams University.
- The researcher obtained an oral consent from study subjects.
- All data was confidential and used only for their benefits and for research purpose.
- A list of participants' patients was separated from the collected data.
- The study subjects were informed that, they had the freedom to withdraw from the study at any time.

Administrative design:

An approval was issued from Faculty of Nursing Ain Shams University to the director of Medical and Nursing directors of the SICU Unit at NCI Cairo University to conduct the study and requesting the permission for data collection from the studied sample.

Operational design:

- **The preparatory phase** :It included reviewing of current and past, national and international related literatures and theoretical knowledge of various aspects of the study using books, articles, periodicals, magazines and internet to develop tools for data collection.
- **Validity and Reliability of the study tools**

Testing validity referred to how well the tools actually measure what it is intended to measure by using face and content validity. Face validity aimed at inspecting the items to determine whether the tools measure what supposed to measure. Content validity was conducted to determine whether the content of the tools cover the aim of the study *(Sharma, 2014)*.

Validity testing ascertained by a group of five experts three from Critical Care Nursing department at Faculty of Nursing at Ain Shams University (two professors and one assistant professors) and one assistant professor from faculty of nursing at Cairo university and one from Medical consultants of the anesthesiology department at National Cancer Institute Cairo University, to test its face and content validity. The jury reviewed the tools for objectivity, comprehensiveness, clarity, relevance, and simplicity. Based on the opinion of the jury, minor modifications were done in Nursing Sensitive Patient Outcomes Measuring Scale.

Reliability of the study tool: The suitable reliability test was carried out to test tool reliability using internal consistency method. They proved a high degree of reliability test in which (alpha = 0.802 for Patients' interview questionnaire and alpha = 0.761 for nursing sensitive Patients' outcomes assessment tool.

- **Pilot Study:**

Before performing the actual study, a pilot study was carried out on 10 patients with epidural analgesia in intensive care unit at national cancer institute in Cairo University hospital to test clarity, efficiency, applicability of the tools and the feasibility of the study process. There was no modification done on the study tool after pilot study, so that, the patients who included in the pilot study were included in the main study group.

Field of work:

The study was carried out through four phases: assessment, planning, implementation, and evaluation. These phases were carried out from beginning of May 2023 until the end of September

through 3days per week (Monday, Tuesday & Wednesday). it took 4 hours from (9 am to 1 pm or from 3 pm to 7 pm) in the previously mentioned setting in morning and afternoon shifts.

Phase I. Assessment phase

- During assessment phase the researcher was prepared tools for date collection.
- The researcher held the first meeting with atients at the Surgical Intensive Care Unit at National Cancer Institute, affiliated to Cairo University Hospitals to introduce herself and briefly explained the nature and the purpose of the study. They were informed that participation in this study was voluntary and they had the right to withdraw at any time. verbal approval from patients to share in this study was achieved.
- The researcher provided an overview and clarification about the tools, then, the structured questionnaire was distributed to each patient to assess demographic characteristic, medical health, knowledge and nursing sensitive outcomes. It was filled by the researcher in a time ranged from 25 to 40 minutes distributed as the following: patient assessment record (patients' demographic characteristics) took about 5 minutes, patients' medical health took about 10 minutes, Nursing Sensitive Patients Outcomes Scale took about 25minutes. The data obtained during this phase constituted the baseline for further comparisons to evaluate the effect of the nursing care on the patient outcomes. The number of group assessed participated ranged from 1-3 group.
- Regarding control group, the assessment was done also as study group and took approximately same time for all data collection tools.

Phase II. Planning phase:

Based on the needs identified in the assessment phase from the participated patients in view the literature. The researcher determined the intervention prptocol

Phase III. Implementation phase:

- Nursing intervention protocol were implemented for the research assistant dealing with the study group according to patients' and nurses learning needs.
- The intervention protocol Structured nursing intervention protocols can enhance the quality of care provided to patients receiving epidural analgesia. These may include:
- ComprehensiveAssessment: Regular assessment of pain levels, vital signs, and neurological status to ensure effective analgesia and detect complications early.
- Assess vital signs every 1 hour.
- Asses insertion site of epidural analgesia to insure from the epidural catheter in its place.
- Assess motor, sensory and concios level during epidural analgesia administration>
- Assess insertion site for any signs of infection, hematoma.
- Change epidural dressing using aseptic technique.
- Change patients position to right or left side to prevent catheter shearing.
- Move the patient from the bed every 8 hrs.
- Reassure the patient by teach him about how to deal with the catheter.
- Encourage patients to express his feeling and ask question to relive anxiety.
- Patient Education :Providing patients with information about what to expect from epidural analgesia, including benefits and potential side effects, can alleviate anxiety and improve satisfaction.
- Give the patients knowledge about definition, indication , care, complications of epidural analgesia.
- Give the patients knowledge about importance and complication of epidural analgesia.

- The observational checklists were filled by researcher and the selected nurses, a through observation of the care provided to the patients with epidural analgesia.
- Data collections were obtained from 2-3 patient per day.

Phase IV. Evaluation phase

Evaluation was emphasized on determining the effect of nursing intervention protocol on nursing sensitive patients' outcomes for patients with epidural analgesia, and patients' complications by comparing the result of study and control by using the same data collection tools which were done to study and control groups.

IV. Statistical design:

All data was collected, tabulated and subjected to statistical analysis. Statistical presentation and analysis of the present study was conducted, using the mean, standard deviation, **unpaired student t-test** was used to compare between two groups in quantitative data, **chi-square test** was used to compare between groups in qualitative, **ANOVA test** was used for comparison among different times in the same group in quantitative data and **linear correlation coefficient** was used for detection of correlation between two quantitative variables in one group by (IBMSPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.).

RESULTS :

Table (1): Comparison of study and control group of patients regarding demographic characteristics. (n=100).

Items	Study		Control		Chi-square	
	N= 0	%	N= 50	%	X2	P-value
Age						
35- <45	7	14	10	20	1.126	0.569
45- <55	34	68	29	58		
55 or more	9	18	11	22		
Mean±SD	46.75±4.37		47.12±5.46			
Gender						
Male	22	44	29	58	1.961	0.161
Female	28	56	21	42		
Marital status						
Married	50	100	50	100		
Education level						
Can't read & write	12	24	11	22	1.329	0.514
Read and write	33	66	30	60		
Bachelor	5	10	9	18		
Work status						
Work	34	68	32	64	0.178	0.673
Not work	16	32	18	36		
Nature of work						
Need muscular effort	4	11.8	4	12.5	0.106	0.948
Need mental effort	17	50	17	53.1		
Need mental & muscular effort	13	38.2	11	34.4		
Residence						
Urban	28	56	30	60	0.164	0.685

Rural	22	44	20	40		

In-significant P>0.05 *P≤0.05significant **P ≤ 0.001 highly significant

Table 1 shows that, there were no statistically significant differences between the study and control group regarding all the demographic characteristic at (p >0.05). Regarding age, mean age of the study group was 46.75±4.37, while mean age in the control group of patients was 47.12±5.46. As regard gender 58% & 44% were male in the control and study group of patients. Also 100% of the study and control group of patients were married, 66% & 60% of them were able to read and write. Concerning work 68% & 64% of the study and control groups of patients were work. In addition to 56% & 60% of the study and control groups of patients were resident in urban area.

Table (2): Comparison of patients' medica data of the study and control groups of patient's**. (n= 100).**

Items	**Control**		**Study**		**Chi-square**	
	N=50	%	N=50	%	X^2	P-value
General medical data						
Smoking						
Yes	17	34	10	20	2.486	0.115
No	33	66	40	80		
If yes						
Cigarette	24	100	14	100		
BMI						
Normal	22	44	19	38	0.915	0.633
Overweight	10	20	14	28		
Obese	18	36	17	34		
Past medical history						
Diabetes Mellites	20	40	21	42	0.041	0.839
Hypertension	17	34	19	38	0.174	0.677
Ischemic Heart Disease	4	8	1	2	1.895	0.169
Past Surgical history						
Previous epidural catheter insertion						
Yes	0	0	3	6	3.093	0.079
No	50	100	47	94		
previous cranium or spine operation						
No	50	100	50	100		

Table 2 the present study shows that, There were no statistically significant differences between the study and control group of patients regarding all their medical and past history at (p >0.05). As regard cigarette smoking, 80% & 66% doesn't smoke in the study and control groups of patients regarding body mass index 38% & 34% of them were obese in the study and control groups of patients. Concerning past medical history 42%, 40 % of them suffering from diabetes Moreover, 38%, 34% of them were hypertensive, 94% &100% doesn't have epidural analgesia before in the study and control group of patients respectively. Also 100% of the study and control groups of patients doesn't make cranium or spine operation.

Table (3): Comparisons of total mean score of physiological health among the study and control groups of patients. **(n=100)**

Items	Control	Study	T-test	
	Mean ±SD	Mean ± SD	T	P-value
gas exchange Indicators	13.42 ±2.26	12.74±1.38	1.816	0.073
Cardiac pump effectiveness Indicators	5.50±0.79	5.58±0.57	0.580	0.564
Peripheral tissue perfusion	5.06±0.91	4.44±0.61	3.991	<0.001*
Circulatory status	3.98±0.84	3.74±0.69	1.552	0.124
Vital signs status	4.78±0.86	4.38±0.67	2.592	0.011*
Pain level	18.16±1.72	17.54±2.12	1.271	0.206
Neurological status	9.54±1.40	8.66±1.00	3.609	<0.001*
Urinary elimination	18.18±2.25	15.96±1.67	5.613	<0.001*
Vomiting & Nausea	13.64±2.69	13.04±1.11	1.461	0.147
Risk for injury	7.34±1.57	6.72±1.73	1.877	0.064
Infection	17.48±1.89	16.90±1.80	1.571	0.119
Physiological health score	117.08±9.79	114.16±8.02	1.631	0.106

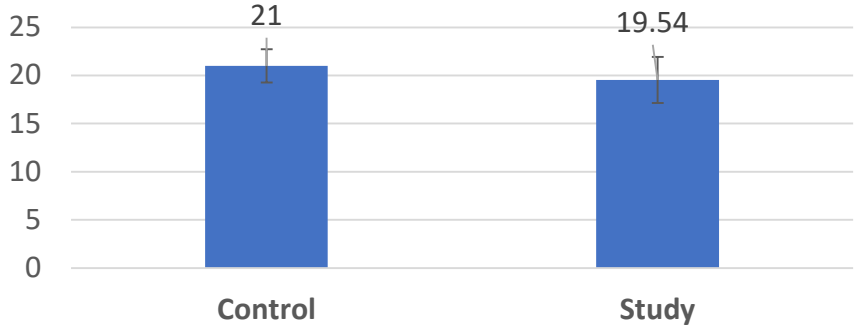
Table 3 shows that, there was statistical significant difference between total mean score of physiological health outcomes among study and control group of patients regarding peripheral tissue perfusion, vital signs status, neurological status and urinary elimination at p-value <0.05*.

Table (4): Comparisons of total mean score of psychological health among the study and control groups of patients. **(n=100)**

Items	Control	Study	T-test	
	Mean ± SD	Mean ± SD	T	P-value
Anxiety control	12.06 ± 1.42	10.78 ± 1.39	4.556	<0.001*
Comfort level	8.94 ± 0.91	8.76 ± 1.27	0.814	0.418
Psychosocial health score	21.00 ± 1.74	19.54 ± 2.38	3.500	<0.001*

Table 4: shows that, there was statistical significant difference between total mean score of psychological health outcomes among study and control group of patients regarding anxiety control and at p-value <0.001*.

Figure (1): Comparisons of total mean score of psychological health outcomes among the study and control groups of patients. (n=100)



This figure show that, there was lower total mean score of psychological health outcomes among study group of patients rather than total mean score of control group of patients.

Table (5): Comparisons of total mean score of health knowledge outcomes among the study and control groups of patients. **(n=100)**

Items	Control		Study		T-test	
	Mean ± SD		Mean ± SD		T	P-value
Epidural catheter care	13.44 ± 1.74		14.86 ± 0.35		5.658	<0.001*
Medication	8.74 ± 1.07		10.04 ± 1.29		5.487	<0.001*
Prescribed activity	9.70 ± 1.47		11.34 ± 0.75		7.020	<0.001*
Infection control	4.90 ± 0.86		5.66 ± 0.59		5.132	<0.001*
Total Health knowledge score	36.78 ± 3.43		41.90 ± 1.64		9.517	<0.001*

Table 5 show that**,** there was statistical significant difference between total mean score of health knowledge outcomes among study and control group of patients regarding Epidural catheter care, Medication, Prescribed activity and Infection control at p-value <0.001*.

DISCUSSION

Epidural analgesia is highly effective for controlling chronic pain such as cancer patients. It can provide pain relief, minimal side effects, and high patient satisfaction when compared with other methods of analgesia. However it can cause serious, potentially life threatening complications. Epidural medications are considered high-alert medications because they may cause significant patient harm when used in error. Patients with long-term epidural catheter has a significant global health concern. Critical care nurses have an important role in patients care to prevent complications. Evaluate the effect of intervention protocol on nursing sensitive outcomes of patients with epidural analgesia for patients with cancer suffering from chronic pain **(Kuroda, 2020).**

According to the demographic characteristics and their medical data in the study and control groups the present study revealed that, there were no statistically significant differences between them. This was important to ensure comparability of the two groups.

The results of the present study revealed that, the mean age of the study group was (46.75±4.37), while also age of the control group was (47.12±5.46), from the researcher point pf view tis may be due to decrease level of awareness about cancer. this finding is consistent with **Asai, et al.,(2020)** in study entitled " Comparision of upper thoracic epidural analgesia versus low thoracic epidural analgesia in off-pump coronary artery bypass graft for perioperative pain management and fast tracking " who found that the mean age of the participant was 46.67±5.44.

In relation to gender, the current study showed that more than half of control group were male and more than two fifth of patients in study groups were male. From the reasercher point of view this finding may be due to males are greater risk for cancer because consume greater quantities of alcohol, smoke cigarettes This finding is consistent with **Wu, et al., (2020)** in study entitled " Effect of epidural analgesia on cancer prognosis after colon cancer resection: a single-centre cohort study in Taiwan" who reported that more than two fifth of the studied sample were male.

As regard marital status, all of the study and control group were married. From the researcher point of view this result may be due to cultures, in addition to culture in our society that people married at young age most patients still married.

As regard to educational level, more than half of the study and control group read and write. From the researcher point of view this finding may be related to increase awareness about importance of education. This finding goes in the same line with **Hasselager, et al., (2022)** in study entitled with “Epidural analgesia and postoperative complications in colorectal cancer

surgery. An observational registry-based study" who mentioned that majority of the sample were educated.

Concerning the work status, the current study revealed that about tow third of the study and control group had work. From the researcher point of view this finding may be due to more than half of patients included in both group in young age group from 45to 55 years old.

Regarding residence, the current study showed that, more than half of patients in the study group and control group lived in urban area. From the researcher point of view this finding might be due to research setting.

Part II: Assessment of patients' medical data among the study and control groups.

Concerning general medical data of cigarette smoking about two thirds of patients in the control group and three quarter of patients in study group weren't smoking. From the researcher point of view this finding may be due to disease process and more than half of the studied and control group were female. This finding goes in the same line with **Hasselager, et al., (2022)** in study entitled with Epidural analgesia and postoperative complications in colorectal cancer surgery. An observational registry-based study" who stated that more than two third of the participant weren't smoking.

As regarding body mass index more than one third of patients in the control and study group suffering from obesity. From the researcher point of view this finding may be due to decrease level of education affect level of health. This finding goes in the same line with **Falk,et al., (2021)** in study entitled with "Comparison between epidural and intravenous analgesia effects on disease-free survival after colorectal cancer surgery: a randomised multicentre controlled trial" who stated that more than third of patients suffering from obesity.

Concerning past medical history of diabetes mellitus more than one third of patients in the control and study group were diabetic. This finding may be due to unhealthy life style. This finding was supported by **Xu,et al., (2021)** in study entitled with Epidural Anesthesia–Analgesia and Recurrence-free Survival after Lung Cancer Surgery: A Randomized Trial" who found that more than third of patients had diabetic.

Concerning past surgical history of previous cranium or spine operation all patients in the study and control group doesn't make any spine or cranium operation. From the researcher point of view this finding may be due to the inclusion criteria of the researcher. This finding goes in the same line with **Falk,et al., (2021)** in study entitled with Comparison between epidural and intravenous analgesia effects on disease-free survival after colorectal cancer surgery: a randomised multicentre controlled trial" who found that all the patients doesn't make any spine or cranium operations.

In relation to total mean score of physiological health among the study and control group, the current study revealed that there was statistically significant difference between total mean score of study and control group of patient regarding peripheral tissue perfusion, vital signs, neurological status and urinary elimination at ($p<0.05$). From the researcher point of view this finding may be related to effect of nursing intervention protocol.

This finding goes in the same line with **Pandraklakis, et al.,(2023)** in study entitled with " Thoracic epidural analgesia as part of an enhanced recovery program in gynecologic oncology: a prospective cohort study. " who found that patients who participated in structured educational session reported improved quality of life and physiological outcomes.

In relation to total mean score of psychological health outcomes among the study and control group, the current study revealed that there was statistically significant difference between total mean score of study and control group of patient regarding anxiety control and psychosocial health

at (p<0.001*). From the researcher point of view this finding may be related to the importance educational program in enhancing patients' knowledge regarding epidural analgesia.

This finding goes in the same line with **Dunkić & Vuletić, (2021).** in study entitled with " Pain and Anxiety Experience in the Choice of Epidural Analgesia in Delivery." Which stated that decreased level of anxiety and pain for patients with epidural analgesia.

In relation to patients` health knowledge outcomes regarding importance of epidural catheter, indication of epidural catheter and nursing care of epidural catheter, contraindication of epidural catheter, complication of epidural catheter. The current study revealeds that majority of the patients in study group had high total mean scores knowledge outcomes post implementation of nursing intervention protocol and there was statistically significant difference between study and control group regarding indication of epidural catheter and nursing care of epidural catheter, contraindication of epidural catheter, complication of epidural catheter at (P< 0.05). From the researcher point of view this finding might be due to the importance of nursing intervention protocol in enhancing patients' knowledge and care regarding epidural analgesia.

This finding goes in the same line with **Cheng, et al.,(2021)** in study entitled with " Satisfaction in parturients receiving epidural analgesia after prenatal shared decision-making intervention: a prospective, before-and-after cohort study " who found that increase level of knowledge of patients regarding epidural analgesia.

This finding is in consistent with **Ali Alahmari, et al.,(2020)** in study entitled with " Knowledge, attitude, and practice of childbearing women toward epidural anesthesia during normal vaginal delivery in Alsanayeah Primary Health Care in Khamis Mushait " which stated that The majority of women of childbearing age had limited knowledge about the benefits and care of epidural analgesia.

In relation to patients` health knowledge outcomes regarding medications side effect and medication precaution. The current study revealed that majority of the patients in study group had positive knowledge outcomes post implementation of educational program and there was statistically significant difference between study and control group regarding medication precaution and correct medications administration at (P< 0.05). This finding might be due to the importance of nursing intervention protocol in enhancing patients' knowledge regarding epidural analgesia medications.

This finding goes in the same line with **Lee and Wu,(2020)** in study entitled with " Educating patients regarding pain management and safe opioid use after surgery: a narrative review " who found that increase level of knowledge of patients regarding epidural medications side effect after nursing intervention about medicatios.

In relation to patients` health knowledge outcomes regarding prescribed activity, activity restriction, activity precaution and proper performance of exercise. The current study revealed that majority of the patients in study group had positive knowledge outcomes post implementation of educational program and there was statistically significant difference between study and control group regarding medication precaution and correct medications administration at (P< 0.05). This finding might be due to the importance of intervention protocol in enhancing patients' knowledge regarding epidural analgesia

This finding goes in the same line with **Jervis Rademeyer, et al ., (2021)** in study entitled with " The effects of epidural stimulation on individuals living with spinal cord injury or disease " who found that increase health knowledge of patient regarding epidural analgesia precaution and activity.

In relation to patients` health knowledge outcomes regarding signs and symptoms of infection and ensure wound site clean. The current study revealed that majority of the patients in study group had high knowledge scores outcomes post implementation of educational program and there was statistically significant difference between study and control group regarding signs and symptoms of infection and ensure wound site clean at ($P< 0.05$). This finding might be due to the high quality nursing management and infection control policy regarding epidural catheter.

This finding goes in the same line with **Cheng, et al.,(2021)** in study entitled with " Satisfaction in parturients receiving epidural analgesia after prenatal shared decision-making intervention: a prospective, before-and-after cohort study " From the researcher point of view this finding may be related to high quality nursing management.

This finding in consistent with **Zhao, et al.,(2021)** in study entitled with " Knowledge, attitude, and practice of childbearing women toward epidural anesthesia during normal vaginal delivery in Alsanayeah Primary Health Care in Khamis Mushait " which stated that The majority of women of childbearing age had limited knowledge about the benefits and side effect of epidural analgesia.

In relation to total mean score of health knowledge outcomes among the study and control group, the current study revealed that there was statistically significant difference between total mean score of study and control group of patient regarding anxiety control and psychosocial health at ($p<0.001$*). From the researcher point of view this finding may be related to effect of the intervention protocol on the health knowledge outcomes.

This finding goes in the same line with **Olaleye, et al., (2022).** in study entitled with " Awareness and Utilization of Obstetric Epidural Analgesia in Labour Among Pregnant Women in Wesley Guild Hospital Ilesha, Nigeria" Which stated that majority of control group had poor knowledge about epidural analgesia and side effect of medication.

This finding was supported by **Dahlberg, et al., (2021),** in the study entitled with "Levels of education and technical skills in registered nurses working in post- anesthesia care units in Sweden Karuna" who stated that, less than one half of the studied nurses had unsatisfactory level of practices related to epidural catheter care.

CONCLUSION

Based on the findings of present study, it can be concluded that:

Based on the findings of present study, it can be concluded that:

There was a significant improvement on patients' nursing sensitive outcomes post implementation of nursing intervention protocol with a highly statistically significant difference at ($P\leq 0.001$) after implementation of intervention protocol among the study and control groups. The implementation of intervention protocol for patients with epidural analgesia has a statistically significant positive effect on their physiological, psychological and health knowledge outcomes which support the stated hypothesis.

Recommendation related to research:

1. Replication of the study on a larger probability sample selected from different geographical area in Egypt is recommended to obtain more generalized data.
2. More research into biological, psychosocial and perceived aspects of health outcomes is needed in order to increase the understanding how to deal with patient connected with epidural analgesia and to develop more effective interventions.
3. Also, more researches should be carried out on a wide international basis to understand variations across communities and to learn more about factors that influence the cause and outcome of patients with epidural analgesia.

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