- *Basic Research*

Effect of Bundled Care on Patients Outcomes with Sepsis during Golden Hour at Intensive Care Units

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Abstract

Background: Sepsis is a possibly fatal disorder which progresses when the body's respond to an infection damages its tissues in addition to organs. Timely intervention, particularly throughout the "golden hour" (the 1st sixty minutes following diagnosis), is critical to improving patient outcomes. Bundled care, which involves the implementation of evidence-based interventions in a structured and timely manner, has emerged as a key strategy for managing sepsis effectively. **Aim:** Assess the effect of bundled care on patients' results with sepsis during golden hour at ICU. **Setting:** The research has been performed at Medicine general adults' intensive care units at Ain Shams University Hospital; Egypt. **Design:** A quasi-experimental/interrupted time-series study and control design has been applied to attain and guide the purpose of the recent study. **Subjects:** A Purposive non-probability/non-randomized sample of 104 adult male & female patients having sepsis were involved in the research. **Tools**: 3 instruments have been utilized to gather information: I- patients' demographic and clinical baseline characteristics, II- the Sepsis Screening Tool and III- the Sepsis bundle outcomes evaluation tool. **Results:** It was revealed that, a high statistically significant variance has been observed between the patient's hemodynamic parameters mean score among control and study groups, while, a statistically significant variance between the patients' average 72-hrs change in SOFA mean score among control and study groups following the implementation of sepsis bundled care during golden hour, with p-value ≤ 0.05, and regarding patients' completion of the hour 1 and 6-hours sepsis bundle the results revealed that, a greatly statistically significant variance among both groups following the implementation of sepsis bundled care during golden hour, p-value <0.001. **The study concluded** that, above two-thirds of the study group were complete the sepsis Hour-1 bundle and sepsis bundle completed within the first 6 hours with a greatly statistically significant variance among both groups following the implementation of sepsis bundled care during golden hour. **The study recommended**; establishing a written update guideline of sepsis care for patients in ICU to confirm giving professional and comprehensive care for patients; it's additionally suggested to implement the recent research in other hospitals in Egypt.

Keywords: Bundled Care, Golden Hour, Intensive Care Unit, Patients Outcomes.

Introduction

Sepsis remains a primary etiology of death and morbidity globally, with quick development from initial infection to life-threatening organ dysfunction demanding immediate, coordinated intervention. The concept of the "golden hour" the critical 1st sixty minutes after diagnosis has emerged as a pivotal window for initiating evidence-based therapies to halt septic progression (Evans et al, 2021).

In intensive care units (ICUs), where patients with sepsis are managed, bundled care has become a cornerstone of clinical practice. These standardized, time-sensitive interventions such as early antibiotic administration, fluid resuscitation, vasopressor support, and lactate measurement are derived from the Surviving Sepsis Campaign (SSC) protocols and aim to address the pathophysiological derangements of sepsis, including hypoperfusion, inflammation, and immune dysregulation (Brown, et al, 2023).

Sepsis bundles allow one to follow multipart methods into significant behavioral changes and describe the key components of care about the diagnosis & treatment of patients having sepsis. The introduction of sepsis bundles improved the results for sepsis patients in intensive care units, allowed for the 1st goal-directed treatment, decreased practice variability and led to a more timely and consistent delivery of evidence-based care. These advantages mostly rely on adherence to sepsis bundles, underscoring the significance of focused performance development projects, like comprehensive educational activities about the sepsis bundle of care (Venkatesh et al, 2021).

Nursing care management for patients with sepsis includes early evaluation and continuous following-up of vital signs, administration of intravenous fluids for resuscitation, timely delivery of proper antibiotic therapy, hemodynamic stabilization using vasoactive agents, maintenance of sufficient oxygenation as well as respiratory support, implementation of strategies of infection control, provision of nutritional support, and providing psychosocial support to patients and their families. It also involves instructing them about the symptoms and signs of sepsis and planning for discharge. Care must be customized for each patient based on their clinical state, disease severity, and institutional protocols (Bokhari & Stuart, 2023).

To maximize the identification of the infection source and guarantee that patients receive timely antibiotic therapy, nurses can have a crucial role in both attaining samples for culture and giving antibiotic treatment. According to the guidelines, the probability that the organism leading to the severe sepsis is increased if multiple culture results reveal the same organism (Dellinger, et al, 2020).

Significance of the study: The reported frequency of sepsis has sharply increased in recent decades, primarily as a result of immunosuppression medication, an increase in invasive operations, and population aging. One of the most common etiologies of admission to intensive care units worldwide is sepsis. Sepsis has a high death rate, but early diagnosis and treatment can greatly lower it while also improving patient outcomes and quality of life (Bokhari & Stuart, 2023). Therefore, the implementation of sepsis bundled care during golden hour at ICUs is effective for improving patients' outcomes, decreasing the stay length, and decreasing the complications rate for these patients.

Aim of the Study

The goal of this recent research is to evaluate the effect of bundled care on patients' outcomes with sepsis during golden hour at intensive care units through:

1- Assessing ICU patients' early manifestations of sepsis.

2- Implementing bundled care sepsis during golden hour at intensive care units.

3- Assessing the effect of bundled care on patients with sepsis outcomes after implementation.

Research Hypothesis
The recent research assumed that:

H 1. Patients who managed by sepsis bundled care will have significant enhancement in clinical outcomes.

H 2. Patients who managed by sepsis bundled care will have significantly decreased length of stay in ICUs.

H 3. Patients who managed by sepsis bundled care will have significantly reduced multiple organ failure SOFA scores following sepsis onset.

Operational Definition:

Sepsis bundled care: refers to a set of proof-based interventions which are implemented together to improve patients' outcomes. These interventions are designed to be completed within specific timeframes to ensure rapid and effective treatment.

Patients' Outcomes: patient's outcomes includes; 72-h change in SOFA, sepsis bundle completion rate, length of time patients spent in ICU, and 28-day mortality.

The Golden Hour: "Golden Hour" in sepsis bundle management refers to the critical first hour after the patient confirmed diagnosis with sepsis and to be completed within the first 6 hours. Rapid and coordinated interventions during this time can significantly improve outcomes, including reducing mortality and morbidity.

Subjects and Methods

A- Research design:
A quasi-experimental/interrupted time-series study/control design has been utilized to guide and attain the purpose of the recent study. As Chow, (2024), stated that this design is a way to enhance upon the interrupted time-series design is to add a control group. It comprises taking a group of measurements at intervals over some duration both prior to and following an intervention of interest in two or more nonequivalent groups.

Research Setting

The research has been performed at Medicine general adults' intensive care units (Medicine intensive care units 1, consists of 17 beds and Medicine intensive care units 2, comprises seventeen beds) with overall thirty-four beds in medicine ICUs at selected Ain Shams university hospital; Egypt.

Subjects
A Purposive non probability/non randomized sample of 104 adult male & female patients with sepsis in MICU for a duration of 6 months from the start of April 2024 to the end of October 2024, who met the inclusion criteria was included, four patients have been dropped out of the research as intervention couldn't be attained. So, 100 adult patients were continuing till the end of the research.

Inclusion criteria

- Adult both gender male/female
- Patients that had an identification of disseminated infection or sepsis.
- Following characteristics of systemic inflammatory response syndrome: (Singer et al., 2016) which involve:
- temperature of the body above thirty-eight degrees Celsius or below thirty-six degrees Celsius.
- Rate of pulse above ninety beat per minute.
- Rate of breathing above twenty breaths per minute or PaCO2 below thirty-two mmHg.
- WBC count above 12,000 per microliter or below 4000 per microliter

Exclusion criteria

- Patients moved out or in hospital.
- Patients who undergoes immunosuppressive treatment.

Sample size:

The sample separated simple randomly into 2 equal groups (the 1st patient has been chosen for implementing sepsis care bundle (study group n=50 patients), managed by sepsis bundled care within first hour and be completed within the first 6 hours. The second patient will select for (control group number=50 patients), managed by the routine intensive care units care for sepsis. Control and study groups' sample homogeneousness was preserved.

Tools of data collection:

Tool I: patients' assessment questionnaire:

It has been designed by the investigators written in English language; it involved 2 parts:

Part 1: patient' s demographic data:

It involved patient's sex, age, Glasgow Coma Scale, number of organs affected, the time to diagnosing sepsis, mechanical ventilation and infection source.

Part 1: patient' s clinical baseline characteristics:

It included patients' clinical data as; Acute Physiology and Chronic Health

Evaluation (APACHE II) score by Sadaka et al., (2017), Sequential Organ Failure Assessment (SOFA) score at sepsis time by Lambden et al., (2019), lactate at the time of sepsis, Lactate level ≥ 2 mmoI/L , Blood glucose level within 6 hrs and , new onset organ dysfunction, hemodynamic variables as; body temperature, heart rate, diastolic and systolic blood pressure, respiratory rate and Oxygen saturation & laboratory investigations as; WBCs, RBCs, hemoglobin, creatinine level, lactate level, low platelets, bilirubin increase and total protein and albumin.

Tool II: Sepsis Bundle Compliance Checklists:

It has been designed by the researchers following reviewing relevant literatures (Williams, 2022 and Schorr et al., 2022) was written in English language; to monitor adherence to Surviving Sepsis Campaign (SSC) bundles (one-hour and six-hour). Sepsis care bundle started within 1 hour and completed within six hours from early diagnosis and treatment of sepsis through utilizing the current protocol and supportive nursing interventions for sepsis.

Sepsis Hour-1 Bundle Components:

1. Determine Lactate Concentration
2. Attain Blood Cultures prior to antibiotics (2 sets)
3. Administer Broad-Spectrum Antibiotics
4. Start quick giving Intravenous Fluids thirty milliliters per kilogram crystalloid for hypotension or lactate concentration ≥ 2 millimole per liter.
5. Maintain Blood Pressure

Sepsis care bundle completed within 6 hrs

1. Initial Resuscitation: deliver a minimum of thirty milliliters per kilogram of crystalloids within the 1st three hours for fluid resuscitation.

2. Administration of Vasopressor to sustain a mean arterial pressure (MAP) of a minimum of sixty-five mmHg.

3. Reassessment of Fluid Status: patient's hemodynamics.

4. Re-check Lactate concentration: If initial lactate was ≥ two millimole per liter.

5. keeping blood glucose ≤ 150 but ≥ 80 mg/dL.

Tool III: Sepsis bundle care outcomes evaluation:

It has been designed by the researchers following reviewing associated literatures ***(***Ayoub, et all., 2022 & Ahmed Sayed, 2020), to assess patient's outcomes after implementation of sepsis care bundle as, SOFA score, Sepsis bundle compliance rate, ICU days & 28-day outcome.

Tools validity and reliability

Validity: evaluating face & content validity of the recommended instruments by a jury of 5 experts four professors of Medical- Surgical Nursing in addition to one assistant professor from Faculty of Nursing, Ain Shams University, who reviewed the tool, for relevance, clarity, understanding, easiness, & comprehensiveness for giving, no modifications were necessary.

Reliability: Alpha Cronbach test has been applied to determine the internal consistency of the research instruments. Sepsis Screening Tool was dependable at (0.92) and Septic bundle results evaluation was dependable at (0.94).

Preparatory phase:

Administrative design: The needed official permission has been attained from the administrators of the Ain Shams University Hospital for collection of data explaining the research purpose to obtain cooperation and permission. To guard the rights of patient in the scope of the research, prior to the 1ry interview, consent has been protected from each patient or relative following they were informed about the aim, nature, and advantages of the research. Patients were additionally informed that participation is completely voluntary and might withdraw at any moment without providing any justification. Anonymity and confidentiality of the information has been assured via testifying that the personal data would be preserved private following being unified with the researchers & patients were reassured that the information will be utilized only for the study purpose.

Ethical considerations

An official permission to performed the suggested research has been attained from the Scientific Research Ethics Committee of the Faculty of Helwan University. Participation in the research was voluntary and patients have been obtained comprehensive data about the research and their roles prior to signing the informed consent. The ethical cosederations have been involved clarifying the nature and aim of the research, indicating the probability to withdraw at any moment. Moreover, the intervention utilized in the recent research is harmless and safe to participants. Values, ethics, and beliefs have been respected.

Pilot Study:

Once permission has been permitted to continue with the suggested research, pilot research has been performed prior to beginning the collection of information on 10 of targeted patients (ten percent of sample) from the previously mentioned setting based on the inclusion criteria. These patients were excluded from the primary sample to evaluate possibility, applicability and clarity of the instruments, and estimate the duration required to gather information to recognize any possible interferences which could meet the researchers & limit with the gathering of information.

I- Implementation phase

Field work: The research has been performed from the start of April 2024 to October 2024, involving the progress of the instruments. It was depending on reviewing current & relevant literature concerning sepsis bundle care and patients' results. The researchers were visiting Medicine intensive care unit three days per week. The purpose of the research has been innocently explained to patients/relatives who accepted to participate in the research earlier gathering of information. The sample has been separated into 2 matched equal groups, control group and study group by using simple random sample method (50 for the study group for sepsis care bundle and 50 for the control group for routine ICU care). Collection of information has been performed by the researchers utilizing the same instruments for the same patient who met inclusion criteria; prior to & following implementation of sepsis bundled care.

The baseline assessment: The 1st duration; the researchers identified themselves and clarified the research's nature to the nurses. The patients' demographic and clinical baseline data were collected from the patients' records, Sepsis Bundle Compliance Checklists and Sepsis bundle care outcomes evaluation was utilized to identify and following-up sepsis disorder in patients admitted to intensive care units for all groups.

The implementation phase: Throughout this stage, once the patient diagnosed with sepsis, the responsible nurse immediately attaining the doctor's prescription for chemistry tests and blood culture, urine or culture are provided from other location of the body suspected cause or origin of infection. Furthermore, the implementation of the sepsis hour 1 care bundle and be completed within 6 hours as the following:

Sepsis Hour-1 Bundle Components:

It is a crucial set of interventions for the early identification and management of sepsis. (Surviving Sepsis Campaign Guidelines, 2021).

1. Determine Lactate Concentration
2. Attain Blood Cultures prior to giving antibiotics (two sets)
3. Administer Broad-Spectrum Antibiotics

4. Start quick giving Intravenous Fluids.
5. Maintain Blood Pressure

Sepsis care bundle completed within 6 hrs (Evans et al., 2022)

The Sepsis Care Bundle within 6 hours includes key interventions which should be completed within the 1st 6 hours of recognizing sepsis to improve patient outcomes.

1. Initial Resuscitation: deliver a minimum of thirty milliliters per kilogram of crystalloids within the 1st three hours for fluid resuscitation.
2. Vasopressor Administration: If hypotension persists following fluid resuscitation initiate vasopressors to sustain a mean arterial pressure of a minimum of sixty-five mmHg.
3. Reassessment of Fluid Status: Reassess the patient's hemodynamics and adjust fluid resuscitation as necessary based on clinical response and ongoing monitoring.
4. Re-check Lactate Concentration: If initial lactate was ≥ two millimole per liter, repeat lactate measurement after resuscitation to guide further intervention.
5. keeping blood glucose ≤ 150 but ≥ 80 mg/dL.

Evaluation phase:

This stage has been highlighted on assessment clinical outcomes in medical intensive care unit for all examined patients by Sepsis Screening Tool and Septic bundle outcomes evaluation for 72-h Change in SOFA, Sepsis bundle compliance rate, length of time patients spent ICU, and 28-day mortality.

Statistical Design:

The information has been encrypted and entered utilizing a personal computer. Statistical Package for Social Science (SPSS) version 26 has been applied. Information was attainable utilizing descriptive statistics in the form of percentages and frequencies. T-test has been used as an inferential statistic has been utilized to study the effect of bundled care on patients' outcomes with sepsis. The chi-square test has been utilized to recognize the association among qualitative parameters and Mean±Standard deviation additionally has been utilized. Statistical significance has been deemed at p value ≤ 0.05, and below 0.001 has been deemed greatly significant.

Results

Table (1) illustrates that, in relation to age, fifty-eight percent and sixty-eight percent of the study and control groups had age ranged between fifty to above sixty years with mean age 44±8.6 years for study group and 42± 7.9 years for control group, correspondingly. Male sex represents 58% of the study group and 68% of control group. Moreover, thirty percent and thirty-six percent of study and control groups had GCS below fifteen. Thirty-two percent and twenty-six percent of study and control groups had above 2 organs affected after sepsis, respectively. In addition, fifty-eight percent and sixty-four percent of study and control groups diagnosed with sepsis within six hours or less, whereas forty-two percent and thirty-eight percent of them identified with sepsis more than 6 hours, respectively. 76% and 74% of study and control groups were non mechanically ventilated.

According to APACHE II score at the time of sepsis 90% and 94% of study and control groups had APACHE II score above seventeen with mean score 6.5±3.2 and 7.6± 6.1, respectively. 44% and 48% of the study and control groups had Lactate equale or more than 2 mmol/L with mean score 15.20 ± 2.75 and 14.10 ± 2.43, respectively. Also, mean blood glucose level

within 24 hrs. were 10.14 ± 4.52 for study group and 9.39 ± 3.56for control group. In relation to new onset of organ dysfunction 36% and 34% of study and control groups had cardiovascular failure, correspondingly, with insignificant variance among the 2 groups; which reflected matched/homogeneity groups.

Table (2) demonstrates a high statistically significant variance has been observed in the mean scores of patients' hemodynamic variables between control and study groups following implementation of sepsis bundled care throughout golden hour, with p-value below 0.001.

Table (3) illustrates a high statistically significant variance in the mean scores of patients' laboratory examinations between control and study groups following implementation of sepsis bundled care throughout golden hour, with p-value below 0.001.

Table (4) illustrates that a statistically significant variance has been detected between the patients' average 72-hrs alteration in SOFA mean score among control and study groups following implementation of sepsis bundled care throughout golden hour, with p-value not higher than 0.05. Whereas a great statistically significant distinction has been detected among them concerning sepsis bundle compliance rate, intensive care unit days, intensive care unit mortality and 28-day finding following implementation of sepsis bundled care throughout golden hour, with p-value below 0.001.

Table (5) shows concerning compliance of sepsis bundle care checklist within one hr. among the study and control groups that there was a highly statistically significant variance between them toward measuring lactate level, obtaining blood cultures before antibiotics (2 sets), giving broad-spectrum antibiotics, start quick giving intravenous fluids thirty milliliters per kilogram crystalloid for hypotension or lactate level ≥ two millimole per liter and preserving blood pressure after implementation of sepsis bundled care throughout golden hour, with p-value below 0.001.

Concerning the compliance of sepsis bundle checklist within 6 hrs. among the study and control groups, there was a high statistically significant variance among them toward completing initial resuscitation; deliver a minimum of thirty milliliters per kilogram of crystalloids within the 1st three hours for fluid resuscitation, reevaluation of fluid status; patient's hemodynamics & preserving blood glucose ≤ 150 but ≥ eighty milligram per deciliters following implementation of sepsis bundled care during golden hour, with p-value under 0.001. Also, there was a statistically significant variance between them toward re-checking lactate level if initial lactate was ≥ 2 millimole per liter, with a p-value not above 0.05. Meanwhile, a great statistically insignificant distinction has been found among them toward giving vasopressor to sustain a mean arterial pressure of at least sixty-five millimeters of mercury, with P-value above 0.05.

Table (1): Demographics and baseline characteristics among study and control patients with sepsis (n=100)

Items	Study group (number=fifteen)		Control group (number=fifteen)		Chi-square	
	N	%	N	%	X^2	P-value
Age (years)						
20 < 35	6	12	4	8	16.6	0.940
35 < 50	15	30	12	24		
50 ≤ 60	29	58	34	68		
Mean±SD	44±8.6		42± 7.9			
Gender						
Female	21	42	23	46	0.167	0.419
Male	29	58	27	54		
Glasgow Coma Scale GCS < 15	15	30	18	36	0.050	0.975
>2 Organs affected	16	32	13	26	0.072	0.965
The time to diagnosing sepsis, ≤ 6 hours	29	58	32	64	1.750	0.417
The time to diagnosing sepsis, > 6 hours	21	42	19	38	0.494	0.781
Mechanical Ventilation						
Yes	12	24	13	26	0.719	0.698
No	38	76	37	74		
APACHE II score <17	5	10	3	6	1.296	0.935
APACHE II score >17	45	90	47	94		
Mean±SD	6.5±3.2		7.6± 6.1			
SOFA Score at Time of Sepsis ≥ 2	34	68	28	56	1.156	0.271
Mean±SD	12.10 ± 4.01		13.57 ± 2.75			
Lactate at the time of sepsis	15.20 ± 2.75		14.10 ± 2.43		1.013	0.307
Lactate ≥ 2 mmol/L	22	44	24	48	1.900	0.387
Blood glucose level within 6h (mg/dL)	10.14 ± 4.52		9.39 ± 3.56		0.0790	0.960
***New Onset Organ Dysfunction**						
Hematologic failure	5	10	4	8	0.183	0.913
Hepatic failure	3	6	2	4	4.879	0.087
Renal failure	10	20	7	14	1.900	0.387
CNS failure	13	26	13	26	2.506	0.286
Respiratory failure	8	16	9	18	4.000	0.135
Cardiovascular failure	18	36	17	34	4.867	0.088

Table (2): Mean scores of the control and study groups concerning hemodynamic parameters following-up after implementation of sepsis bundled care during golden hour (n=100)

Items	Study group (number=fifteen) **Mean ± standerd deviation**	Control group (number=fifteen) **Mean ± standerd deviation**	**T test P-value**
Body temperature	2.70±0.53	81.54±0.7	50.619 0.000*
Heart rate	2.50±0.64	11.34±0.5	48.882 0.000*
SBB Systolic blood presuure SBP > 90 mm Hg	2.38±0.60	11.68±0.8	25.781 0.000*
DBB Diastolic blood pressure	2.64±0.66	1.90±0.73	28.182 0.000*
Respiratory rate	2.54±0.57	1.62±0.78	36.529 0.000*
Oxygen saturation	2.50±0.64	1.72±0.45	28.796 0.000*

**Highly Significant P-vallue under 0.001*

Table (3): Mean scores of the control and study groups concerning to laboratory examinations following implementation of sepsis bundled care during golden hour care (n=100)

Items	Study group (number=fifteen) **Mean ± standerd deviation**	Control group (number=fifteen) **Mean ± standerd deviation**	**T test P-value**
White blood cells	6.74± 1.35	11.2±2.12	74.749 0.000*
RBCs Red blood cell	4.46±1.70	8.82±2.59	40.320 0.000*
Hemoglobin	3.98±1.20	7.36±1.10	88.909 0.000*
Creatinine	2.34±0.59	1.52±0.7	37.451 0.000*
Lactate Measurement	2.37 ± 1.47	5.12 ± 1.15	38.772 0.000*
Low platelets	0.90±0.46	1.88±0.65	27.506 0.000*
Bilirubin increase	1.74±0.89	4.14±1.63	32.024 0.000*
Total protein	2.34±0.59	1.52±0.78	29.720 0.000*
Albumin	2.28±0.57	1.46±0.50	31.373 0.000*

**Highly Significant P-value under 0.001*

Table (4): Comparative analysis of the studied groups with regard to patients' finding after implementation of sepsis bundled care throughout golden hour (number=100)

patients' outcomes	Study group (number=fifteen)		Control group (number=fifteen)		Chi-square	
	N	%	N	%	X^2	P-value
SOFA score Average 72-h Change in SOFA	23	46	22	44	8.833	0.012*
Mean ± SD	30.9±9.4		27.4±12.5			
Sepsis bundle completion rate	27	54	19	38	15.209	0.000**
ICU days						
< week	23	46	11	22	18.087	0.000**
One week	20	40	25	50		
> week	7	14	14	28		
ICU mortality	12	24	22	44	35.756	0.001**
28-day outcome						
Dead	13	26	23	46	14.704	0.001**
Alive	37	74	27	54		

**Significant (S), P≤ 0.05* ***Highly Significant P-value under 0.001*

Table (5): The Compliance of sepsis bundle care checklists between the control and study groups (n=100)

Sepsis bundles	Study group (number= fifteen)		Control group (number=fifteen)		Chi-square	
	N	%	N	%	X^2	P-value
Within first 1 hr.						
1. Measure lactate level	50	100	39	78	23.930	0.000**
2. Blood culture before antibiotics (two sets)	48	96	41	82	13.512	0.001**
3. Administer broad-spectrum antibiotics	49	98	39	78	19.000	0.000**
4. Begin rapid administration of Intravenous Fluids	47	94	41	82	17.981	0.000**
5. Maintain blood pressure	50	100	27	54	26.431	0.000**
Be completed within the first 6 hrs. **1. Initial Resuscitation: deliver at least 30 mL/kg of crystalloids within the 1st 3 hours for fluid resuscitation.**	50	100	32	64	0.017*	0.000**
2. Vasopressor Administration to maintain a mean arterial pressure of at least 65 mmHg.	50	100	50	100	1.900	0.387
3. Reassessment of Fluid Status: patient's hemodynamics.	50	100	21	42	21.793	0.000**
4. Re-check Lactate Level: If initial lactate was ≥ 2 mmol/L.	50	100	41	84	8.100	0.017*
5. Blood sugar ≤ 150 (≥ 80) mg/dL	43	86	23	46	14.704	0.001**

**Significant (S), P≤ 0.05* ***Highly Significant P-value under 0.001*

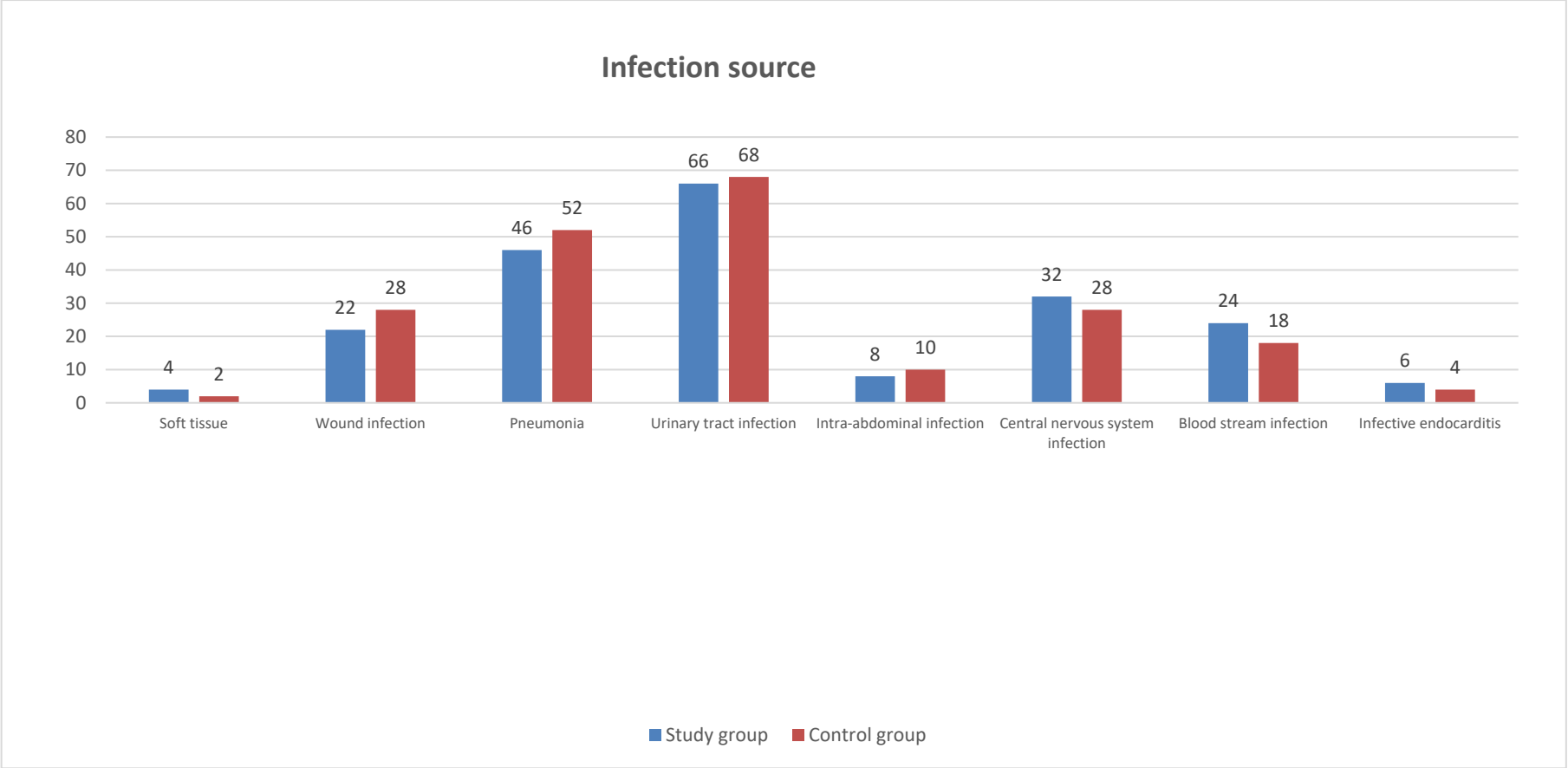

Figure (1) Distribution of infection source of sepsis between study and control groups (number=100)

Figure (1) explains that (66%) and (68%) of both control and study groups had urinary tract infection as the main etiology of sepsis, correspondingly. Furthermore, a statistically insignificant variance has been observed between all groups (X2=4.879, p-value equal to 0.087), that reflected matched/homogeneity groups.

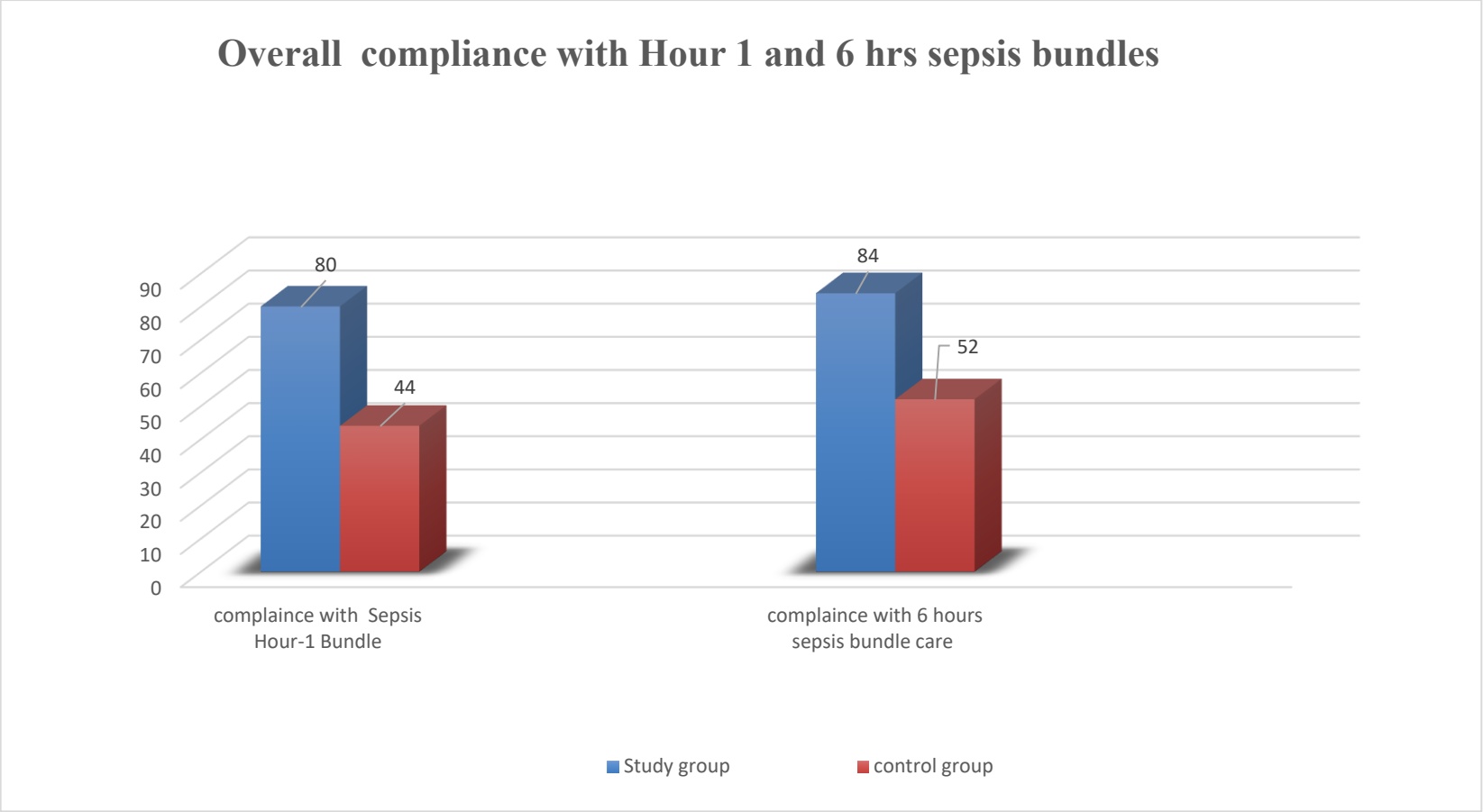

Figure (2) Distribution of overall compliance with one hr. and six hrs. sepsis bundles between the study and control groups (number=100)

Figure (2) clarifies that 80% and 44% of both study and control groups were complaint with 1 hr. sepsis bundle, respectively. Also, 84%and 52% of them were complaint with 6 hrs. sepsis bundle, correspondingly. With a greatly statistically significant variance among all groups following the implementation of sepsis bundled care throughout golden hour, p-value below 0.001.

Discussion:

Sepsis is a critical condition that can result in various life-threatening complications, including septic shock, numerous organ dysfunction, and organ failure. In spite of progressions in technology and healthcare facilities, sepsis is still a serious and often fatal condition that affects millions of people both domestically and internationally. Patient outcomes depend on managing the host's response and dropping hypoperfusion of organ and tissue damage as well as the infection (Singer et al., 2022).

The following discussion is divided into two main sections. The first section presents the results of the patients' demographic and baseline medical data, while the second section addresses the 1st associated hypothesis: "The study group which underwent sepsis bundled care will demonstrate significant improvements in clinical outcomes, a reduction in the length of stay in the medical intensive care unit, and a significant decrease in the SOFA scores for multiple organ failure following the onset of sepsis."

The current study on sepsis bundled care aims to evaluate the effect of bundled care on patients' outcomes with sepsis throughout golden hour at intensive care units., the period of stay for septic patients in the intensive care unit, and the ICU fatality rate. From the researchers' perspective, in spite of variances in the etiologies or origins of infection, it is unlikely that the timing of the initiation of the sepsis care bundle implementation in the outcomes was significantly affected by these factors. The underlying etiology of the illness is one of the risk factors for sepsis. Additionally, during close monitoring, patients may not have been promptly recognized, with the 1ry focus being on the activation and implementation of the sepsis care bundle. This is supported by Rhodes et al. (2023) who are found that, while the study and control groups had different diagnoses and infection causes, this had no bearing on the triage nurses' adherence to sepsis protocols. When applying for a care bundle, the cause of infection influences the decision. In contrast, the paper done by Farrell & Casserly, (2018) who are verified that any postponements in handling all four advice of sepsis care recommendations, even if they did not exceed the 3-hour window is related to an important increase in in-hospital mortality.

The 1st section investigates the baseline medical information and baseline characteristics of both the study and & groups. Two matched groups have been included in the study, and a statistically insignificant variances have been observed among them in any demographic group. This proposes that bias has been minimized, validating the groups homogeneity. The findings of recently investigation demonstrated that the mean age of the examined patients was 44±8.6 and 42± 7.9 for the study and control groups, respectively. Additionally, over half of all groups there age were among 50 and 60 years old, whereas above half of the control & study groups of the research were men and nearly all of the two groups had Acute Physiology and Chronic Health Evaluation II scores of more than seventeen with mean scores of 6.5±3.2 and 7.6± 6.1, Sayed (2020) consistent with the recent outcomes a statistically insignificant variance has been found among the study and control groups concerning all items of demographic characteristics, but found a dissimilar finding that above half the control group was women & nearly half of them in-study group were men & (APACHI score) in study group was reduced in comparison with the control group with a considerable difference .Whereas the outcomes of the study carried out by Chou et al. (2023) indicate that the median age was seventy-four years with a median Acute Physiology and Chronic Health Evaluation II score.

Conversely, the recent research illustrated that about two-thirds of both control and study groups had urinary tract infection as the 1ry cause of sepsis with statistically insignificant variance among all groups that reflected matched/homogeneity groups &, this finding is in accordance

with Chou et al. (2023) who stated that the urinary tract infection is the 1st primary etiology of sepsis in the intensive care unit, whereas this outcome is contradicted with Levy, et al., (2022) who are expected hospital death above other illnesses and showed that pneumonia is the cause of sepsis, from the researchers point of view this finding is associated with the urinary catheterization and the immobility of the patients in the ICU.

As regards the hemodynamic parameters monitoring the current investigation revealed a great statistically significant variance between the patient's hemodynamic parameters mean score among control and study groups following the implementation of sepsis bundled care throughout golden hour, from the researcher's insight the precise hemodynamic profiling is important for confirming proper supporting actions and, eventually, better results. this result in line with Valeanu, et al, (2021) who is demonstrated that, critically ill patient hemodynamic variables may be enhanced following the implementation of the sepsis bundled care particularly in the golden hour. Conversely, Patel, et al (2023) clarifies that, the cornerstones of successful care include goal-directed hemodynamic resuscitation, efficient source control, and the early provision of appropriate antimicrobial medication.

Regarding overall compliance with hour 1 bundle and sepsis bundle completed within 6 hours among the study and control groups, the current study clarifies that more than two-thirds of the study group were compliant with the hour 1 & 6 hrs sepsis bundle with a greatly statistically significant variance among all groups following the implementation of sepsis bundled care throughout golden hour. This outcome is in line with Raj, et al, (2019) who is found the baseline compliance of compound 6 mechanisms of 6 hr sepsis restoration package was little and knowingly enhanced on post-intervention

Concerning laboratory examinations, the recent research shows a great statistically significant variance between the patients' laboratory investigations mean score among study and control groups after the implementation of sepsis bundled care throughout golden hour, from the researcher's view these outcomes reflect the effectiveness and importance of applying the sepsis care bundle in the intensive care unit. These results is in line with Arthur & Zanten, (2024) who are documented although the "golden hour" for antibiotics in sepsis and septic shock has been established, we must prevent getting off to a false start when it comes to antibiotic abuse, to ensure that future patients undergo sufficient antibiotic treatment, critical care antibiotic stewardship is essential.

The current investigation reveals there was a statistically significant variance between the patients' average 72-hrs change in SOFA mean score between control and study groups following implementation of sepsis bundled care throughout golden hour. Furthermore, a great statistically significant variance has been detected between them concerning sepsis bundle compliance rate, ICU days, ICU mortality, and 28-day result following implementation of sepsis bundled care throughout golden hour, this result is in agreement with Sayed (2020), the evidence-based care bundle group saw a more than 50% reduction in the frequency of ICU deaths.

Based on the researcher's point of view, implementing a sepsis care bundle for patients with sepsis entails teamwork to quickly identify patient who may have sepsis, perform important evaluations, and give immediate treatments that improve results of the patient & the sepsis care bundle interventions are successful in reducing sepsis rates due to routine risk factor

recognition and removal. Critical care nurses, conversely, were essential in identifying and triaging patients who might have sepsis, starting the implementation of the care bundle, and lowering the ICU mortality rate. In summary, the results of this investigation corroborated earlier research demonstrating the use of sepsis care bundle and their implementation greatly.

Conclusion:

Based on the result of the present investigation and research hypothesis, the study concluded that:

Above two-thirds of the research group were compliant with the hour one- and six-hours sepsis bundle with a highly statistically significant variance among all groups after the implementation of sepsis bundled care during golden hour. In addition, a statistically significant variance has been observed between the patients' average 72-hrs alteration in SOFA mean score between control and study groups following implementation of sepsis bundled care throughout golden hour. Also, there was a high statistically significant difference among them concerning sepsis bundle compliance rate, ICU days, ICU mortality, and 28-day result following implementation of sepsis bundled care throughout golden hour.

Recommendations:

- Availability of updated sepsis protocol and guidelines in surgery and emergency ICU based on standard and universal sepsis screening tools.
- Provide periodic in-service training depending on best practice guidelines for health team who work in intensive care units & emergency units with regard to early identification of sepsis and organ dysfunction.
- Replication of the research utilizing substantial cohorts at various ICUs in Egyptian.
- Enhancing and promoting patient compliance with evidence-based therapies should be the main goal of any effort made to reduce hospital mortality from severe sepsis.

References:

1. Arthur R. H. van Zanten, MD, PhD. (2024). The Golden Hour of Antibiotic Administration in Severe Sepsis: Avoid a False Start Striving for Gold. Copyright © 2024 by the Society of Critical Care Medicine and Lippincott Williams & Wilkins DOI: 10.1097/CCM.0000000000000363.
2. Venkatesh, B., Schlapbach, L., Mason, D., Wilks, K., Seaton, R., Lister, P., ... & Rice, M. (2022). Impact of 1-hour and 3-hour sepsis time bundles on patient outcomes and antimicrobial use: a before and after cohort study. *The Lancet Regional Health–Western Pacific*, *18*.
3. Bokhari, A. M., & Stuart, M. (2023). Bacterial Sepsis: Practice Essentials, Background, Etiology. Medscape Reference. Retrieved March 29, 2023.
4. Brown, M., Lahori, S., Montgomery, A., Dong, Y., Gajic, O., & Niven, A. (2023). 996: MAXIMIZING THE GOLDEN HOUR IN CRITICALLY ILL PATIENTS: ASSESSMENT GAPS AT THE TIME OF ADMISSION. *Critical Care Medicine*, *51*(1), 491.
5. Farrell, C., & Casserly, B. (2018). Sepsis, the earlier the better, 3-to 1-hour bundle. *Journal of Emergency and Critical Care Medicine*, *2*.
6. Dellinger, R. P., Levy, M. M., Rhodes, A., Annane, D., Gerlach, H., Opal, S. M., ... & Surviving Sepsis Campaign Guidelines Committee including the Pediatric Subgroup. (2020). Surviving sepsis campaign: international guidelines for management of severe sepsis and septic shock: 2012. *Critical care medicine*, *41*(2), 580-637.

7. Evans, L., Rhodes, A., Alhazzani, W., Antonelli, M., Coopersmith, C. M., French, C., ... & Levy, M. (2021). Surviving sepsis campaign: international guidelines for management of sepsis and septic shock 2021. *Critical care medicine*, *49*(11), e1063-e1143.
8. Patel, G. P., Gurka, D. P., & Balk, R. A. (2003). New treatment strategies for severe sepsis and septic shock. *Current opinion in critical care*, *9*(5), 390-396.
9. Lambden, S., Laterre, P. F., Levy, M. M., & Francois, B. (2019). The SOFA score—development, utility and challenges of accurate assessment in clinical trials. *Critical Care*, *23*, 1-9.
10. Levy, M. M., Dellinger, R. P., Townsend, S. R., Linde-Zwirble, W. T., Marshall, J. C., Bion, J., ... & Parker, M. M. (2022). The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. Intensive care medicine, 36(2), 222- 231.
11. Valeanu, L., Bubenek-Turconi, S. I., Ginghina, C., & Balan, C. (2021). Hemodynamic monitoring in sepsis—a conceptual framework of macro-and microcirculatory alterations. *Diagnostics*, *11*(9), 1559.
12. Andrew, R., Evans Laura, E., Waleed, A., Levy Mitchell, M., Massimo, A., Ricard, F., ... & Phillip, D. R. (2017). Surviving sepsis campaign: international guidelines for management of sepsis and septic shock: 2016. *Critical Care Medicine*, *18*(2), 197-204.
13. Rhodes, A., Phillips, G., Beale, R., Cecconi, M., Chiche, J. D., De Backer, D., ... & Girardis, M. (2023). The surviving sepsis campaign bundles and outcome: results from the international multicenter prevalence study on sepsis (the IMPreSS study). Intensive care medicine, 41(9),1620-1628.
14. Rudd, K. E., Johnson, S. C., Agesa, K. M., Shackelford, K. A., Tsoi, D., Kievlan, D. R., ... & Naghavi, M. (2020). Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. *The Lancet*, *395*(10219), 200-211.
15. Sadaka, F., EthmaneAbouElMaali, C., Cytron, M. A., Fowler, K., Javaux, V. M., & O'Brien, J. (2017). Predicting mortality of patients with sepsis: a comparison of APACHE II and APACHE III scoring systems. *Journal of clinical medicine research*, *9*(11), 907.
16. Sayed, A., Z. (2020). Effect of evidence-based sepsis care bundle on patient outcome in Medical Intensive Care Unit. *Egyptian Journal of Health Care*, *11*(2), 826-836.
17. Schorr, C. A., Seckel, M. A., Papathanassoglou, E., & Kleinpell, R. (2022). Nursing implications of the updated 2021 Surviving Sepsis Campaign guidelines. *American Journal of Critical Care*, *31*(4), 329-336.
18. Chou, S. L., Chan, K. S., Cheng, K. C., Chou, W., Hung, H. M., & Chen, C. M. (2024). The implementation of sepsis bundles on the outcome of patients with severe sepsis or septic shock in intensive care units. *International Journal of Gerontology*, *8*(2), 60-65.
19. Singer, M., Deutschman, C. S., Seymour, C. W., Shankar-Hari, M., Annane, D., Bauer, M., ... & Angus, D. C. (2016). The third international consensus definitions for sepsis and septic shock (Sepsis-3). *Jama*, *315*(8), 801-810.
20. Singer, M., Deutschman, C. S., Seymour, C. W., Shankar-Hari, M., Annane, D., Bauer, M., ... & Angus, D. C. (2016). The third international consensus definitions for sepsis and septic shock (Sepsis-3). *Jama*, *315*(8), 801-810.
21. Surviving Sepsis Campaign Guidelines (2021). International Guidelines for Management of Sepsis and Septic Shock 2021. Critical Care Medicine: October 4, 2021. Available at: Surviving Sepsis Campaign Guidelines 2021 | SCCM
22. Raj, S. K., Panda, P. K., Wig, N., Agarwal, P., & Pandey, R. (2019). Compliance with 6 h-Sepsis resuscitation bundle of surviving Sepsis campaign before and after resident Physicians' training: a quality improvement interventional Study among Indian patients. *Journal of Emergencies, Trauma, and Shock*, *12*(1), 3-9.
23. Williams, B. (2022). The national early warning score: from concept to NHS implementation. Clinical Medicine, 22(6), 499-505.

الملخص العربي

تأثير حزمة الإجراءات على نواتج المرضى المصابون بالانتان خلال الساعة الذهبية فى وحدات العناية المركزة

المقدمه: الإنتان مرضٌ قد يكون مميتًا، ويتطور عندما تُلحق استجابة الجسم للعدوى الضرر بأنسجته وأعضائه. يُعدّ التدخل في الوقت المناسب، وخاصةً خلال "الساعة الذهبية" (أول ستين دقيقة بعد التشخيص)، أمرًا بالغ الأهمية لتحسين نتائج المرضى. وقد برزت الرعاية المُجمّعة، التي تتضمن تطبيق تدخلات قائمة على الأدلة بطريقة منظمة وفي الوقت المناسب، كاستراتيجية رئيسية لإدارة الإنتان بفعالية.

الهدف: تقييم تأثير الرعاية المُجمّعة على نتائج مرضى الإنتان خلال الساعة الذهبية في وحدة العناية المركزة. **المكان:** أُجري البحث في وحدات العناية المركزة للبالغين بكلية الطب في مستشفى جامعة عين شمس، مصر.

التصميم: طُبّقت دراسة شبه تجريبية/متقطعة ذات سلاسل زمنية مُتتالية وتصميم ضابط لتحقيق هدف الدراسة الحديثة وتوجيهه. المشاركون: شارك في البحث عينة هادفة غير احتمالية/غير عشوائية من 104 مرضى بالغين من الذكور والإناث مُصابين بالإنتان. الأدوات: تم استخدام ثلاث أدوات لجمع المعلومات: *I*- الخصائص الديموغرافية والسريرية الأساسية للمرضى، *II*- أداة فحص الإنتان، و*III*- أداة تقييم نتائج حزمة الإنتان.

النتائج: وقد تبين أنه لوحظ وجود تباين كبير ذي دلالة إحصائية بين متوسط درجات معايير الديناميكية الدموية للمريض بين مجموعتي المراقبة والدراسة، بينما كان هناك تباين ذو دلالة إحصائية بين متوسط التغير في درجة *SOFA* لدى المرضى لمدة 72 ساعة بين مجموعتي المراقبة والدراسة بعد تنفيذ حزمة الرعاية الخاصة بالإنتان خلال الساعة الذهبية، بقيمة $p \leq 0.05$، وفيما يتعلق بإكمال المرضى لحزمة الرعاية الخاصة بالإنتان لمدة ساعة و6 ساعات، كشفت النتائج عن وجود تباين كبير ذي دلالة إحصائية بين المجموعتين بعد تنفيذ حزمة الرعاية الخاصة بالإنتان خلال الساعة الذهبية، بقيمة$p > 0.001$.

الخلاصه والتوصيات: خلصت الدراسة إلى أن أكثر من ثلثي مجموعة الدراسة أكملوا حزمة الرعاية الخاصة بالإنتان لمدة ساعة واحدة وحزمة الرعاية الخاصة بالإنتان التي تم إكمالها خلال أول 6 ساعات مع وجود تباين كبير ذي دلالة إحصائية بين المجموعتين بعد تنفيذ حزمة الرعاية الخاصة بالإنتان خلال الساعة الذهبية. أوصت الدراسة؛ - وضع دليل مكتوب محدث لرعاية مرضى الإنتان في وحدة العناية المركزة للتأكد من تقديم الرعاية المهنية والشاملة للمرضى؛ كما يقترح تنفيذ الأبحاث الحديثة في مستشفيات أخرى في مصر.