

Effect of Implementing Nursing Care Bundle upon Perineal Trauma Reduction and Birth Outcomes during Vaginal Birth

Ghada Abd El-Salam Belal¹, Doaa Samir Elkhawaga², Anaam Ebrahim El-Nagar³

¹Assistant Professor of Maternal and Neonatal Health Nursing, Faculty of Nursing, Tanta University, Tanta, Egypt

^{2,3}Lecturer of Maternal and Neonatal Health Nursing, Faculty of Nursing, Tanta University, Tanta, Egypt

Abstract

Perineal trauma may negatively affect a woman's life, leads to short- and long-term maternal morbidities. Care bundle is now a common approach to improve the care quality and patient outcome over the past decade. It serves as a method of motivating health professionals to act in accordance with accepted best practices that can be implemented consistently and collectively to a unique patient during a clinical episode. **The study aim:** Evaluate the effect of implementing nursing care bundle upon perineal trauma reduction and birth outcomes during vaginal birth. **Subjects and Method:** A Quasi-experimental research design was used. **Subjects:** A purposive sample of 130 women has been selected from antenatal clinics and labor units of obstetrics departments at; Tanta University Hospital, El-Mobara and El-Menshawey General Hospital. **Four tools were utilized: Tool (I): Women' Labor Parameters Assessment Sheet. Tool (II): Birth Outcome Assessment sheet. Tool (III): Perineal trauma Observational Checklist. Tool IV: Visual Analogue Scale (VAS). Results:** After application of the nursing care bundle, a significant reduction of perineal trauma/ tears and pain as well as maternal and newborn complications was documented among the nursing care bundle group in contrast to the routine hospital care group. **Conclusion:** The nursing care bundle implementation comprising evidence-based interventions performed collectively was effective in reducing perineal trauma and pain as well as improving birth outcomes. **Recommendations:** The nursing care bundle application must be integrated in nursing education and ongoing in-service training programs for maternity nurses.

Keywords: Nursing Care Bundle, Perineal trauma, Birth outcomes.

I.Introduction:

Globally, an approximate 90% of vaginal births lead to some genital tract trauma, particularly among primipara women (Persson, Lindberg, & Öhman, 2023). The incidence of Egypt perineal lacerations is unobtainable, however a few studies found that the incidence of perineal trauma among Egyptian women is relatively high (Abd-Ella, Kandeel, & Gouda, 2021; El-Sayed, Lashin, Mohammed, & Abo El-Fath 2022; Mohamed, Abd Ella, Hassan & Khedr 2017).

The risk factors of perineal trauma are modifiable and non-modifiable risk factors. The modifiable risk factors are instrumental vaginal delivery and positions of maternal birth as lithotomy, and sitting (Jansson et al., 2020). While, the non-modifiable risk factors include primiparity, higher maternal age, post-term birth, macrosomic baby >4 kg, edema of the perineum, and a prolonged second stage of labor (Jansson et al., 2020). Health care providers set a top priority on limiting the perineal trauma and lowering any potential related morbidity (Thomas, & Jayabharathi, 2016). It is imperative to concentrate on enhancing clinical care in order to decrease these risk factors and reduce the perineal trauma development. The identification of the risk factors enables obstetrical practice to be modified with the intention of decreasing the perineal trauma incidence and its concomitant related morbidity (Okeahialam, Sultan, & Thakar, 2024).

Perineal trauma may negatively affect a woman's life, whereas around half (50%) of these trauma leads to short- and long-term maternal morbidities. This is directly linked to the degree or the extent of perineal

trauma and its complexity. Approximately 6% of impacted women will suffer from short-term maternal morbidities including; infection and bleeding, that can lead to constipation and urinary retention; prolonged recovery; extension of episiotomy to the rectum; slow bonding between the mother and her newborn and disruption of maternal-infant interaction. While, long-term maternal morbidities such as; anal sphincter rupture, anorectal malfunction, anal region incontinence, dyspareunia, recto-vaginal fistula, genital tract prolapse and perineal pain. Additionally, perineal trauma can result in incapacitating physical, psychological, and social issues that can negatively affect the family's overall quality of life (Aquino et al., 2020; Balachandran, Wong, & Thakar, 2022).

In the past, perineal protection was a top concern and priority for nurses, and there are still differing views on perineal protection today (Bidwell et al., 2021). It is important to prevent perineal trauma during childbirth. Identifying and modifying risk factors would reduce trauma to the perineum. Although, specific antenatal risk factors as fetal weight and body mass index are unmodifiable at the time of birth. Therefore, techniques to prevent perineal trauma during antenatal and childbirth would be beneficial to a large number of women. (Balachandran, Wong, & Thakar, 2022)

Many techniques are suggested to improve perineal outcomes such as; massage of the perineum at the third trimester of pregnancy which aims to reduce muscular resistance of the perineal muscles, maintaining sexual activity during pregnancy, and pelvic floor muscle training (PFMT) (Balachandran, Wong, & Thakar,

2022). Also, encouraging women to adopt position of lateral recumbent, kneeling, squatting, or semi-recumbent position in labor and delivery (Balachandran, Wong, & Thakar, 2022). In addition, the utilization of warm perineal compress during the second stage of labor and as reflected in UK guidelines and utilizing one of two techniques to safeguard the perineum during the fetal head crowning and delivery of the posterior shoulder (National Institute for Health and Clinical Excellence 2017). They are; the hands-on technique, which advises applying pressure to the advancing vertex and/or stretching perineum and the hands-poised approach, which promotes little contact with the perineum (Bidwell et al., 2021).

Any intervention to prevent perineal trauma must identify which components or elements that directly impact woman care, namely; standardized optimal care, and evidence-based practice (OASI Care Bundle Project Team. (2018). As a result of this, care bundle is now a common approach to enhance the care quality and patient outcome over the past decade. Its origin is the United States Healthcare Improvement Institute which first defined care bundles in 2001 as a small set of evidence-based interventions that, when implemented together, will result in significantly better outcomes than when implemented individually (Gilhooly, Green, McCann, Black & Moonesinghe 2019; Resar, Griffin, Haraden & Nolan, 2012)

Ideally, a care bundle needs to be concise and straightforward, containing a minimum of three to five evidence-based procedures, intervention, recommendations, or practices applied consistently and collectively with the aim to boost the care quality and patient outcomes (Gilhooly et al., 2019). They are utilized extensively across the healthcare facilities with the goal to avoid and handle numerous health conditions (Lavallée, Gray, Dumville, Russell & Cullum 2017).

The premise for bundle of care utilization is based on the idea that it includes elements which may be applied to a unique patient in one clinical episode, so that each bundle application is self-contained by all health care professionals, every time and in their entirety, then both care quality and outcomes are enhanced. Care bundle serves as a method of motivating health professionals to act in accordance with accepted best practices (OASI Care Bundle Project Team 2018).

In light of the rising trends of the novel care bundle that include an evidence-based actions and the increased rate of perineal trauma and obstetric anal sphincter injuries (OASI) incidences in England, a national experts team met to discuss plans to lower the perineal trauma and OASI incidence and developed the OASI Care Bundle project (Bidwell, et al., 2018; Jurczuk, et al., 2021). The Royal College of Obstetricians and Gynecologists (RCOG) and the

Royal College of Midwives (RCM) provided the leadership, support and evaluation of this work (Royal College of Obstetricians & Gynecologists, Royal College of Midwives. 2016). Then, a stepped wedge cluster randomized trial was used across 16 maternity units across England, Scotland and Wales (2017-2018) to determine the care bundle effectiveness. This care bundle included; informing women about OASI and identifying what can be done to lower or reduce her risk, performing an episiotomy when required, manual perineal protection and a thorough rectal examination after vaginal birth to assess perineal trauma (Balachandran, Wong, & Thakar, 2022; Bidwell et al., 2018; Gurol-Urganci et al., 2021). The women's self-reported experience -es with the use of perineal care bundles during delivery were positive. Women stated that they sensed empowered and supported, especially when health care providers were able to communicate effectively (Bidwell et al., 2021). Obstetricians and local midwives facilitated the OASI Care Bundle application of inside each unit. These "champions" of clinical obtained centralized education and training during multidisciplinary skills development days (Bidwell et al., 2021). Moreover, in 2018, 28 member hospitals of the Women's Healthcare Australasia (WHA) introduced the WHA bundle with the aim of decreasing the rate of severe perineal trauma (SPT). The bundle includes five interventions: perineal warm compresses, manual perineal support (hands on the fetal head and the woman's perineum), medio-lateral episiotomy applied at a minimum 60-degree angle if indicated, and genito-anal examination for all women following labor & birth and evaluate perineal lacerations and grading by two health care providers (Women's Healthcare Australasia 2019).

Significance of the study:

To date, limited or no evidence based care bundle for perineal trauma prevention developed in Egypt. Given that, preventing perineal trauma and its after effects or implications, including perineal pain, dyspareunia, incontinence, and genital prolapse, is a crucial outcome for parturient women. Therefore, new guidelines as care bundle might greatly raise the perineal trauma detection rate to prevent the occurrence of undetected trauma, which is a duty violation that could lead to legal action (Bidwell et al., 2021). So, it was essential to determine the effect of implementing nursing care bundle upon perineal trauma reduction and birth outcomes during vaginal birth.

Hopefully, the findings of this study will provide data that will be valuable in the practice of maternity nurses and other health care professionals. Furthermore, the outcomes of this study may aid in improving the service quality provided to primipara women, which will affect their future life.

II. Aim of the study:

This study aimed to:

- Determine the effect of implementing nursing care bundle upon maternal and fetal outcomes.
- Evaluate the effect of implementing nursing care bundle upon perineal trauma reduction during vaginal birth.
- Evaluate the effect of implementing nursing care bundle on improving birth outcomes during vaginal birth.

Research hypothesis:

- Implementing nursing care bundle is expected to decrease perineal trauma during vaginal birth than the routine hospital care.
- Implementing nursing care bundle is expected to reduce adverse birth outcomes during vaginal birth than the routine hospital care.

Operational definitions:

The nursing care bundle: It is a small set of evidence-based interventions for a defined patient segment and care setting that when implemented together will result in significantly better outcomes than when implemented individually.

In this study, nursing care bundle comprised a set of 4 practices or precautionary steps including; antenatal information (informing women about perineal trauma and what can be performed to decrease her risk), warm compresses applied to the perineum, the use of hands-on technique, and a systemic examination of the vagina and ano-rectum.

Perineal outcomes:

Refers to the perineal condition after vaginal delivery as; intact perineum, episiotomy, presence of perineal trauma or tear, degree of perineal tear and perineal pain intensity.

III. Subjects and Method:

Study Design: Quasi-experimental research design was used to conduct this study.

Quasi-experimental design is a research methodology used to study the effects of independent variables on dependent variables when full experimental control is not possible or ethical.

Setting: The study was carried out at antenatal clinics and labor units of obstetrics departments at;

- Tanta University Hospital affiliated to Ministry of Higher education and Scientific Research.
- El-Mobara hospital which was affiliated to Health Insurance.
- El-Menshawey General Hospital affiliated to Ministry of Health and Population

The outpatient clinics at Tanta University Hospital were located in the outpatient clinics building in the second floor and included one antenatal clinic with one examining bed. The labor unit also was located in the second floor and consisted of two rooms, each one comprised of three labor beds. The outpatient clinic at El-Mobara hospital was located in the second floor and consisted of one room with one examining bed while the labor unit also was located

in the second floor and consisted of two rooms, each one was with three labor beds. The outpatient clinic at El-Menshawey hospital was located in the third floor and contained one antenatal clinic with three examining bed. Also, the labor unit also was located in the third floor and consisted of one room with one labor beds.

Subjects: Purposive samples of 130 pregnant women were chosen from the previously settings listed above. They were selected based on the inclusion criteria listed as follow; the age range was from 20-35 years, pregnant with a single viable fetus, 38 to 42 weeks of gestation, primipara, free from antenatal or pre-existing medical conditions that predisposing to a complicated birth, and whose fetus has not been diagnosed prior to labor to be at risk of complications (as congenital malformations, intrauterine growth restriction, and placental problems).

The subjects were separated into two equal groups:

The control group: 65 women who received the routine hospital care.

The study group: 65 women who received the nursing care bundle.

The sample size was calculated using Steven Thimpsons equation:

Steven Thimpsons equation

$$n = \frac{N \times P (1-P)}{\{(N-1) \times (d^2 / Z^2) + P (1-P)\}}$$

n=Sample size

N=Total society size

d=error percentage = (0.05)

P=percentage of availability of the character and objectivity= (0.5)

Z= The corresponding standard class of significance 95%= (1.96)

Data collection tools:

Four tools were used to achieve the aim of this study.

Tool I: Women's Labor Parameters Assessment Sheet: This tool was developed by the researchers and comprised three parts.

Part (1): Socio-demographic characteristics of women: included; age, residence, educational level, occupation, income and family type.

Part (2): Reproductive history: This included gestational age at current labor and delivery, gravidity, abortion and body mass index.

Part (3): Labor parameters: The researchers developed this part after reviewing the recent related literatures (**Abd-Ella, Kandeel & Gouda, 2021; Abdel Monem, El-Habashy & Yonis, 2020; Sarhan, Kassem, Gamal, & Khalil, 2022**) to assess the labor parameters. It included; progress of labor (spontaneous or induced labor), membranes (ruptured or intact), Liquor (absent or clear), primary delivered (anterior or posterior shoulder), duration of the second and third stage of labor in minutes, need for

pain relief in labor and its type, perineal care and intake of prophylactic antibiotics.

Tool II: Birth Outcome Assessment sheet: It was adapted from (Abd-Ella, Kandeel & Gouda 2021; Aasheim, Nilsen, Reinar & Lukasse, 2017; El-Sayed et al., 2022; Modoor, Fouly & Rawas 2021; Sarhan et al., 2022) and comprising two parts:

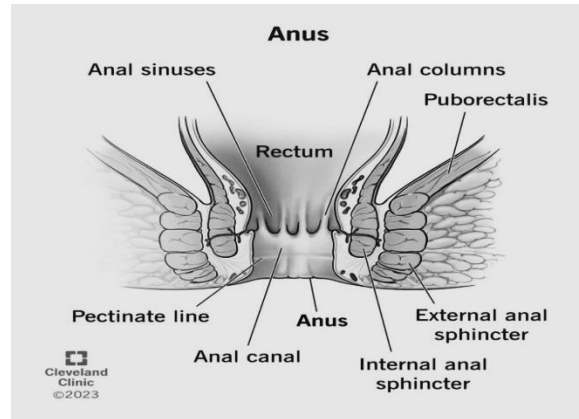
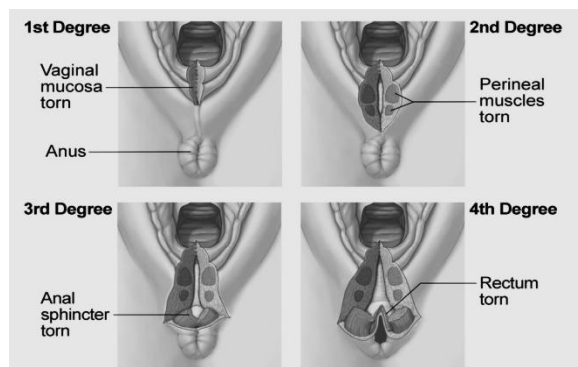
Part (1): Assessment of maternal outcomes: It consisted of; presence of maternal complications, need for postpartum analgesia more than usual and intake of parenteral non-steroidal anti-inflammatory drugs (NSAIDS) (number of ampoules).

Part (2): Assessment of newborn outcomes: It comprised; newborns birth weight (kg), Apgar score at 1st and 5th minutes and presence of newborn complications.

Tool III: Perineal trauma Observational Checklist:

This tool adopted from Sultan (1999) and it was adopted and published by (Committee on Practice Bulletins-Obstetrics, 2018); Roper, Amber, Wan, Sultan, & Thakar, 2020); Royal College of Obstetricians and Gynecologists (RCOG, 2015), to assess the degrees of perineal trauma as follow:

Classification of perineal trauma	
Degree	Injury
Intact	No visible tear.
First	Injury to perineal skin and/or vaginal mucosa.
Second	Injury to the perineum involving perineal muscles but not involving the anal sphincter.
Third	Injury to the perineum involving the anal sphincter complex which subdivided into: Grade 3a tear : <50% thickness of external anal sphincter (EAS) torn. Grade 3b tear: >50% thickness of EAS torn. Grade 3c tear: Both EAS and internal anal sphincter (IAS) torn
Fourth	Injury to the perineum involving the anal sphincter complex (EAS and IAS) and anorectal mucosa.



<https://my.clevelandclinic.org/health/body/2478/4-anus-function>

Tool IV: Visual Analogue Scale (VAS):

This pain rating scale was used for the first time in 1921 by Hayes and Patterson as mentioned in (Delgado et al., 2018). It is a self-reported 10-point numerical rating scale corresponding to the level of pain as follows: **Zero (no pain), 1-4 (mild pain), 4-7 (moderate pain), 7-10 (severe pain) and 10 (unbearable pain)**. It was used to assess the intensity of perineal pain.

Method:

The following steps were used to implement the study:

1. Administrative design: A formal letter explaining the aim of the study was acquired from the Faculty of Nursing and delivered to the responsible authorities of the previously mentioned settings to conduct the study.

2. Ethical considerations: The acceptance of an ethical committee was given with a code number 455-4-2024. The women’s informed consent was obtained for participation, after clarifying the study aim. Also, the study' nature didn't cause any harm for the whole sample. Additionally, confidentiality and privacy were guaranteed with regard to the collected data and each participant was allowed for withdrawal at any time from the study.

3. Tools development: The researchers developed **Tool I, and Tool II** after verifying the recent related literatures and then tools were tested for face and content validity by jury test of 5 experts in the field of Maternal and Neonatal Health Nursing to evaluate the items and the entire tool as being pertinent and suitable for testing the desired outcome. The face validity of the tools was calculated based on experts' view and it was 96% and the content validity index (%) of its items was 94%. **While, the validity Tool IV** In the absence of a gold standard for pain, criterion validity cannot be evaluated. For construct validity, in patients with a variety of rheumatic diseases, the pain VAS has been displayed to be highly correlated with a 5-point verbal descriptive scale (“nil,” “mild,” “moderate,” “severe,” and “very severe”) and a numeric rating scale (with response

options from “no pain” to “unbearable pain”), with correlations ranging from 0.71–0.78 and 0.62–0.91, respectively (Downie et al., 1978).

4. The Pilot Study: A pilot study was carried out prior to the actual collection of data on 10% of the total sample (13 pregnant women) at the previously selected settings, to ascertain the clarity, feasibility and applicability of the developed tools. The data obtained from the pilot study were included as no major changes in the tools were made.

5. Assessment of the reliability of the translated Arabic tools was tested by the pilot subjects for calculating Cronbach's Alpha that was 0.904 for women' labor parameters assessment sheet, 0.930 for birth outcome assessment sheet. While, the **Tool III** reliability used in this study was adopted from (RCOG, 2015). The reliability of tool Cronbach's Alpha = 0.71, so it is highly reliable. In addition, the **Tool IV** Test–retest reliability has been shown to be good, but higher among literate ($r= 0.94, P= 0.001$) than illiterate patients ($r = 0.71, P= 0.001$) before and after attending a rheumatology outpatient clinic (Ferraz et al.,1990). High reliability when it is used for acute abdominal pain and ICC= 0.99 [95%CI 0.989 to 0.992]. (Gallagher, Bijur, Latimer, & Silver, 2002).

5-The Field of Work: Collection of data was carried out over a six months period from the beginning of (May 2024 to October 2024) at Tanta University Hospital, El-Mobara and El-Menshaway hospitals.

The subsequent phases were utilized for the data collection:

I- Assessment and planning phase:

During this phase, the researchers first met the pregnant women during the third trimester between (38 and 42 weeks) at the antenatal visit, introducing themselves to the participants, and the aim of the study was clarified for obtaining the consent of women to participate in the study. For collection of base line data, the study and control groups were interviewed individually using **tool I part 1 and 2**. Then, the researchers took women' permission to take their phone number and call them to be with them at the time of labor and delivery in both groups. In addition, the researchers prepared the nursing care bundle brochure for the study group, using simple Arabic language and different illustrative pictures that included **firstly** detailed information about perineal trauma and the nursing care bundle with steps that should be taken to minimize the perineal trauma risk during labor. Then, the study group was given a nursing care bundle brochure copy at the antenatal interview.

II- Implementation phase:

The hospital routine care was provided to the control group during the second stage of labor (maintained head flexion during its expulsion).

The researchers then implemented the **second** nursing care bundle throughout the second stage of labor at crowning for each woman in the study group, which include applying perineal warm compresses to the perineum and external genitalia, from the beginning of the second stage until bulging of the head. It was made by soaking perineal pads (gauze) or clean washcloths placed in warm tap water with a temperature ranged from 45C-59°C that was measured by lotion thermometers, and then each perineal pad gently applied to the perineal area after squeezing and replaced every 15 minutes to insure suitable temperature. The researchers frequently checked the perineal area for erythema, and the compress was removed in case of excessive erythema. Also, the **third** nursing care bundle applied to the study group was the use of hands-on technique or sometimes called Manual Perineal Protection (MPP). It is an obstetric intervention applied at the end of the second stage of labor. One hand is used to “cup” the fetal head and control the speed and progress of the presenting part. The other hand supports the perineum using the thumb and forefinger on the lower part of the labia, firm pressure is used while flexing the remaining three fingers and pushing them against the perineum thus facilitating the fetal head delivery with the least possible diameter. As the face becomes visible, the middle finger of the perineal support hand was used to assist with the birth of the chin over the introitus. The woman was encouraged to refrain from pushing and breathe the baby out slowly. While still supporting the perineum waiting for restitution to occur, the woman was encouraged to push gently to birth the shoulders. The researchers continue hands-on technique throughout the birth of the shoulders by moving the non-dominant hand to support the baby's body. Finally, the researchers applied gentle axial traction until both shoulders is born. (Kleprlikova et al., 2020); Martínez et al., 2021)



Recumbent/semi-recumbent Position

<https://www.mkuh.nhs.uk/wp-Perineal-Trauma-df>

The **fourth** nursing care bundle is a systematic perineal examination, including a per rectum examination, during the fourth stage of labor. This assessment performed even with the intact perineum. Any tears were documented using **tool III**.

III- Evaluation phase:

After collecting the baseline data at the third trimester using (**tool I part 1, 2**), the researchers used (**tool I part 3**) during the second stage of labor to assess the labor progress for the study and control groups, and **tool II part 1, 2** to assess the maternal and newborn outcomes during the third stage of labor. While, **tool III** was used to assess the degrees of perineal trauma and **tool IV** assessed the degree of perineal pain three times for the study and control groups before application of care bundle, immediately after application of care bundle, and at third stage of labor after placental delivery.

The study and control groups were compared to evaluate and determine the effect of nursing care bundle upon perineal trauma reduction and birth outcomes during vaginal birth.

Statistical analysis:

The data collected were organized, coded, entered, tabulated and analyzed by using appropriate statistical method and tests. The Statistical Package for Social Sciences SPSS (SPSS) version 25.0 was used (IBM Corporation, Armonk, NY, USA).

For quantitative data, the range, mean and standard deviation were calculated. For qualitative data, which describe a categorical set of data by frequency, percentage or proportion of each category, comparison between two groups and more was done using Chi-square test (χ^2).

For comparison between means of two groups of parametric data of independent samples, student t-test was used. For comparison between means of two groups of non-parametric data of independent samples, Z value of Mann-whitney test was used.

Results:

Table (1): Shows that (44.6%) of the study group aged from (>25-30) years as opposed to 36.9% of the control group with no statistically difference between them. As regard to residence, it was revealed that 52.3% were from urban areas unlike that the same percentage of the control group that resides in rural regions. Concerning the level of education, it was observed that (56.9% & 43.1% respectively) of the study and control groups had Secondary/ Diploma. Additionally, the same table points out that the highest percent of the study participants were housewives with (64.6%) for the study group corresponding to 72.3% for the control group. The percentage of study and control groups with insufficient income was as high as 78.5% and 61.5%, respectively according to woman's view. Furthermore, it was found that (53.8% & 50.8%) among the study and control groups respectively were living with nuclear family.

Table (2): Illustrates that the mean gestational age at current labor and delivery was (40.18±1.14 & 40.00±1.24 respectively) between the study and control groups, and there was no statistically

significant difference between them (P=0.379). Also, it clearly showed that (64.6%) of the study group was either primigravida and had no abortion corresponding to (60% & 58.5%) of the control group respectively. At the same table, (56.9%) of the study group had healthy weight compared to 44.6 of the control group.

Table (3): Represents that the mean duration of the second and third stages of labor/minutes, it was explained that the study group's duration during the second and third stages of labor was shorter. (90.15±24.08 & 22.23±4.59 respectively) than the control group (100.23±23.79 & 24.85±6.84 respectively) whose differences are statistically significant (P=0.018* & 0.012*). At the same time, the table demonstrates that the need of pain relief in labor is less in the study group (46.2%) corresponding to (84.6%) of the control group with the study and control groups differing statistically significantly (P=0.0001*).

Table (4): Shows birth outcomes of the study participants which were portrayed through maternal outcomes and proved that only (21.5%) of the study group had complications after birth whereas, (50.8%) of the control group experienced complications with a difference between them that is statistically significant (P=0.001*). Whereas, in relation to newborn outcomes, it was obvious that the study and control groups' mean newborn birth weights (Kg) were within the normal range (3.42±0.49 & 3.34±0.46), and there was no statistically significant difference (P=0.358). Additionally, the first-minute Apgar scores for the study and control groups fell within the normal range (8.00±1.01 & 7.00±1.86 respectively) without a difference that is statistically significant (P=0.051), however, the study group's Apgar score at the fifth minute was higher (9.00±0.96) than the control group's (8.00±1.69), and the two groups' differences were statistically significant (P=0.036*).

In addition, the presence of newborn complications indicates that new complication affected 23.1% of the study group in comparison to 53.8% of the control group, a statistically significant difference (P=0.0001*).

Figure (1): Points out perineal outcomes after birth including perineal condition and presence of perineal trauma which illustrates that (53.8%) of the study group had intact perineum compared to (13.8%) among the control group and (46.2% & 86.2% respectively) of them undergone episiotomy. As regard to the presence of perineal trauma, a decrease in perineal trauma was seen with only 6.2% in the study group versus 86.2% in the control group, and a statistically significant difference between the two groups in terms of trauma and perineal condition (P=0.0001* & P=0.0001*, respectively).

Figure (2): Stands for the perineal tear degree; it was found that the study group suffered from only first

and second degree perineal tear (75% & 25% respectively) from only four cases of perineal trauma. Meanwhile, perineal tears of the first, second, third, and fourth degrees were reported (50.0% & 28.6%, 14.3% & 7.1) among the study participant of the control group respectively.

Figure (3): Elucidates that prior to the application of the nursing care bundle, the study participants' perineal pain intensity was severe and unbearable (60.0% & 36.9%, respectively), corresponding to (44.6% & 55.4%, respectively) among the control group prior to routine hospital care; however, there was not a statistically significant difference between

them ($P=0.053$). Only 6.2% of the study group experienced severe pain immediately following the application of the nursing care bundle, compared to 40% of the control group, which experienced severe pain immediately following routine hospital care. This difference between the two groups was statistically significant ($P=0.0001^*$). However, at the third stage of labor following placenta delivery, the study group's perineal pain intensity was still lower (10.8%) than that of the control group (27.7%), with a statistically significant difference between the two groups ($P=0.0001^*$).

Table (1): Sociodemographic characteristics of the studied women.

Sociodemographic characteristics	The studied women (n=130)				χ^2 test P value
	Study group (n=65)		Control group (n=65)		
	n	%	n	%	
♦Age years:					
20-25	18	27.7	23	35.4	1.081
>25-30	29	44.6	24	36.9	0.582
>30-35	18	27.7	18	27.7	
♦Residence:					
Rural	31	47.7	34	52.3	0.277
Urban	34	52.3	31	47.7	0.599
♦Educational level:					
Illiterate	4	6.2	4	6.2	7.167
Read and write	4	6.2	8	12.3	0.306
Primary/ Preparatory	3	4.6	8	12.3	
Secondary/Diploma	37	56.9	28	43.1	
University	17	26.2	20	30.8	
♦Occupation:					
Housewife	42	64.6	47	72.3	1.213
Working	23	35.4	18	27.7	
Official	11	16.9	7	10.8	0.545
Unofficial sector	12	18.5	11	16.9	
♦Income:					
Enough	14	21.5	25	38.5	4.432
Not enough	51	78.5	40	61.5	0.035*
♦Family type:					
Nuclear	35	53.8	33	50.8	0.123
Extended	30	46.2	32	49.2	0.725

*Statistically significant ($P<0.05$)

Table (2): Reproductive history of the studied women.

Reproductive history	The studied women (n=130)				χ^2 test P value
	The study group (n=65)		Control group (n=65)		
	n	%	n	%	
◆Gestational age at current labor and delivery (weeks):					
38-40	44	67.7	47	72.3	0.330
41-42	21	32.3	18	27.7	0.566
Range	38-42		38-42		
Mean±SD	40.18±1.14		40.00±1.24		
t-test	0.883				
P value	0.379				
◆Gravidity:					
Once	42	64.6	39	60.0	1.111
Twice	20	30.8	20	30.8	0.574
Three times	3	4.6	6	9.2	
◆Number of abortion:					
None	42	64.6	38	58.5	1.224
Once	20	30.8	21	32.3	0.542
Twice	3	4.6	6	9.2	
◆BMI on antenatal booking (kg/m2):					
Healthy weight	37	56.9	29	44.6	2.436
Underweight	10	15.4	14	21.5	0.487
Overweight	10	15.4	10	15.4	
Obesity	8	12.3	12	18.5	

Table (3): Labor parameters of the studied women.

Labor parameters	The studied women (n=130)				χ^2 test P value
	The study group (n=65)		Control group (n=65)		
	n	%	n	%	
♦Labor progress:					
Spontaneous	44	67.7	34	52.3	3.205
Induced	21	23.3	31	47.7	0.073
-If induced, oxytocin drops/minute					
5 drops/min	21	100	19	61.3	13.382
10 drops/min	0	0	12	38.7	0.001*
♦Membranes:					
Intact	34	52.3	16	24.6	10.530
Ruptured	31	47.7	49	75.4	0.001*
♦Liquor:					
Absent	34	52.3	16	24.6	10.530
Clear	31	47.7	49	75.4	0.001*
♦Primary delivered:					
Anterior shoulder	45	69.2	37	56.9	2.144
Posterior shoulder	20	30.8	28	43.1	0.146
♦Duration of the second stage of labor (min.):					
Range	60-100		60-150		
Mean±SD	90.15±24.08		100.23±23.79		
t-test (P value)	2.400 (0.018*)				
♦Duration of the third stage of labor (min.):					
Range	15-30		15-40		
Mean±SD	22.23±4.59		24.85±6.84		
t-test (P value)	2.558 (0.012*)				
♦Need for pain relief in labor:					
No	35	53.8	10	15.4	21.242
Yes	30	46.2	55	84.6	0.0001*
-If yes, mention the type of pain relief in labor					
Regional	30	100	55	100	-
♦Perineal care:					
No	3	4.6	20	30.8	15.266
Yes	62	95.4	45	69.2	0.0001*
♦Intake of Prophylactic antibiotics:					
No	1	1.5	8	12.3	5.849
Yes	64	98.5	57	87.7	0.016*

*Statistically significant (P<0.05)

Table (4): Maternal and newborn outcomes of the studied women.

Maternal and newborn outcome	The studied women (n=130)				χ^2 test P value
	The study group (n=65)		Control group (n=65)		
	n	%	n	%	
♦Maternal outcome:					
▪Presence of maternal complications:					
No	51	78.5	32	49.2	12.030
Yes	14	21.5	33	50.8	0.001*
▪Need for postpartum analgesia more than usual					
No	34	52.3	24	36.9	3.113
Yes	31	47.7	41	63.1	0.078
▪ Intake of parenteral NSAIDS(number of ampoules):					
No	15	23.1	3	4.6	41.499
One ampoule	45	69.2	23	35.4	0.0001*
Two ampoules	5	7.7	37	56.9	
Three ampoules	0	0	2	3.1	
♦Newborn outcome:					
▪Newborn birth weight (Kg)					
Range	2.50-3.70		2.50-4.00		
Mean±SD	3.42±0.49		3.34±0.46		
t-test (P value)	0.923 (0.358)				
▪Apgar score at first minute:					
Range	5-9		0-9		
Mean±SD	8.00±1.01		7.00±1.86		
Z value (P value)	1.950 (0.051)				
▪ Apgar score at fifth minute:					
Range	6-10		3-10		
Mean±SD	9.00±0.96		8.00±1.69		
Z value (P value)	2.102 (0.036*)				
▪Presence of newborn complications:					
No	50	76.9	30	46.2	13.000
Yes	15	23.1	35	53.8	0.0001*

*Statistically significant (P<0.05)

NSAIDS=Non-steroid ante inflammatory drugs.

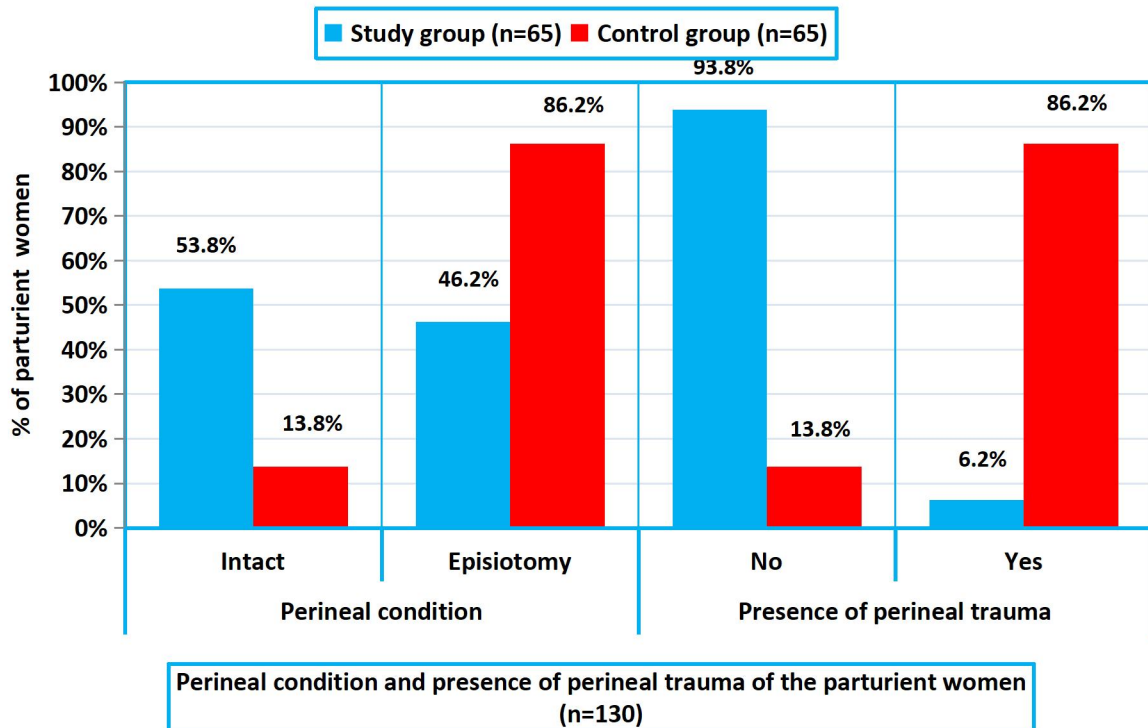


Figure (1): Percent distribution of the studied parturient woman according to their perineal condition and presence of perineal trauma (n=130).

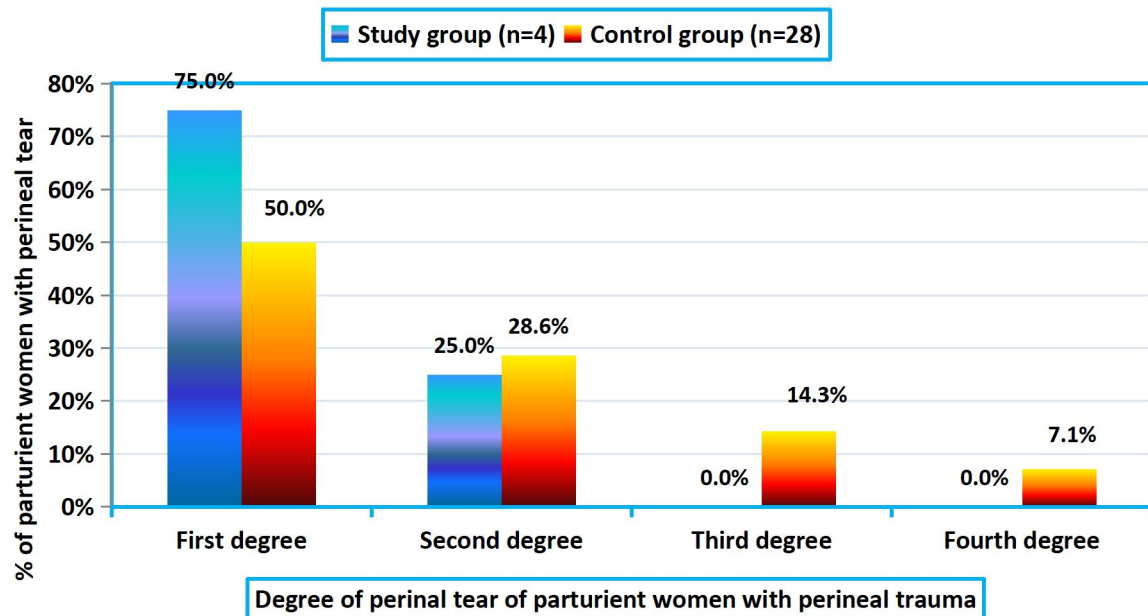


Figure (2): Percent distribution of the studied parturient women according to degree of perineal tears (n=130).

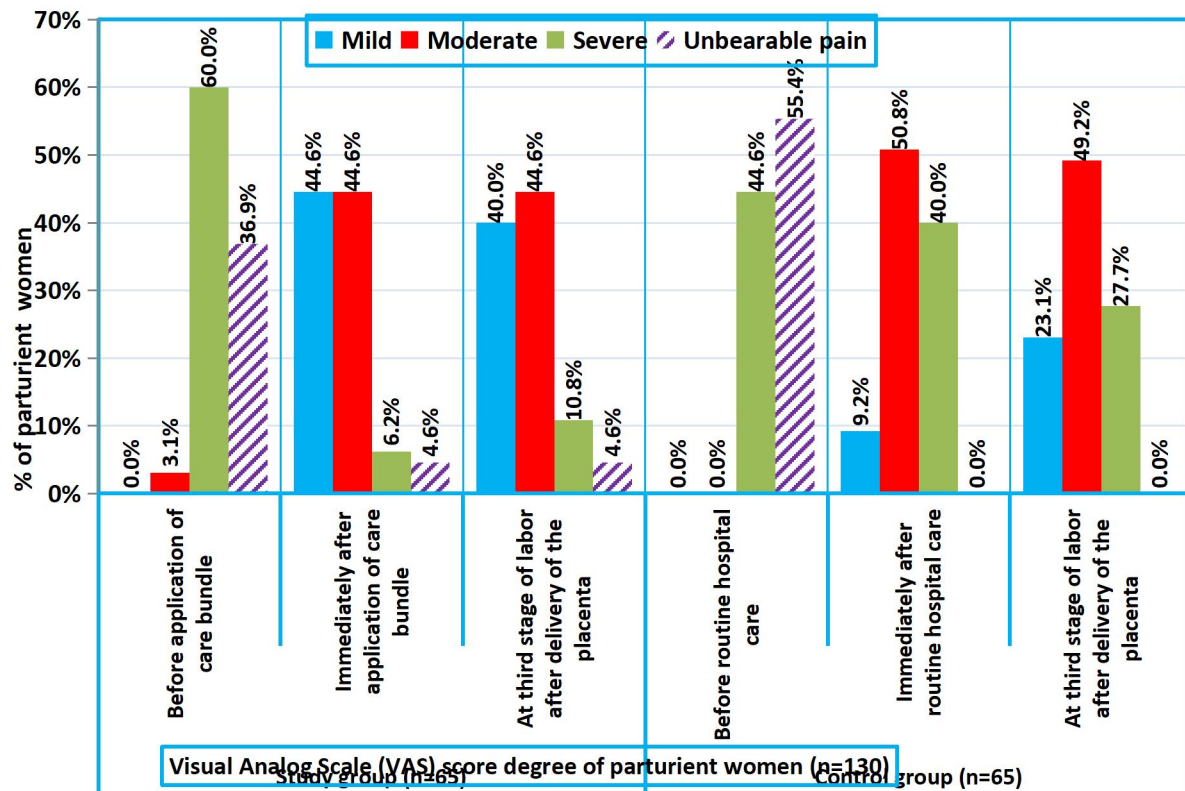


Figure (3): Percent distribution of the studied parturient woman regarding perineal pain intensity according to visual analogue scale (n=130).

Discussion:

One of the most common serious complications is perineal trauma during vaginal birth especially among primipara women. It can adversely affect the woman's quality of life and postpartum recovery. Short or long-term physical and psychological complications resulting from perineal trauma and tears could cause morbidity (Aguiar et al., 2019). The rate of perineal trauma highlights the requirement for efficient preventative strategies to lower its morbidity and enhances maternal health and wellbeing. One of these strategies is the perineal protection care bundle, which a grouping of evidence-based interventions is designed to lessen clinical practice variability that could lead to less desirable outcomes. (Lee et al., 2024). Thus, the current study was carried out to evaluate the effect of implementing nursing care bundle upon perineal trauma reduction and birth outcomes during vaginal birth.

The care bundle in this study includes; providing woman with antenatal information regarding the prevention of perineal trauma, using hands-on techniques, applying warm compresses to the perineum, and performing a systemic examination of the ano-rectum and vagina.

The current study's findings demonstrated that there was no discernible difference between the study participants and the control groups with respect to the socio-demographic characteristics

and reproductive history as they match in almost all of their aspects. This matching and no significant difference are beneficial for the potential of the study results to be generalized in addition to minimizing the impact of the cofounding variables that may impede the utilization's effect of care bundle on perineal outcomes during the second stage of labor.

This result was consistent with (Abdel Monem, El-Habashy & Yonis, 2020), and Bulchandani, Watts, Sucharitha, Yates, & Ismail, 2015), as well as (Ibrahim, Elgzar & Hassan, 2017). They stated that no statistically significant difference was detected between the study participants in their control and study groups in relation to socio-demographic characteristics and reproductive histories. In the same context, another supported study conducted by Fahami, Shokoohi, Kianpour, Norbakhsh, & Heidari (2012), found that the three groups of women under study weren't significantly different in terms of age, education, place of residence, occupation, or family income. In addition, (Gaheen and Abo Hatab, 2021), mentioned that the participants of the studied groups and control group did not differ statistically significantly as regard to their socio-demographic characteristics. As well as, (El-Sayed et al., 2022), found that regarding demographic data and reproductive history, there were no appreciable differences between the groups under study.

Moreover, a study conducted by (Sarhan et al., 2022), highlighted the fact that the three groups under study are similar in almost every way with respect to their demographic data with no significant differences among them.

Regarding labor parameters of the studied parturient women, both the study and control groups differed statistically significantly with regard to the duration of the second and third stages of labor. This clarified that the care bundle application group had a mean second stage of labor duration that was shorter than that of the control group. These study results concurred with (Gaheen and Abo Hatab, 2021), they found that when comparing the three intervention groups to the control group, the mean duration of the second stage of labor is shorter. Also, (Goma, Khedr & Gouda, 2020), revealed that the second stage of labor was statistically significantly shorter for the hand-on group than for the hand-off group. From the researchers' viewpoint, the findings' similarities could be explained by the fact that they share some of the evidence-based elements used in the care bundle applied in our study that prove its effectiveness.

Meanwhile, this finding contradict with (El-Sayed et al., 2022), their results reported that neither warm compresses applied to the perineum nor lubricated perineal massage during the second stage of labor had shortened the duration of the second stage as compared to the control group, and no significant difference identified between the groups under study in this regard. Also, (Ganji, Shirvani, Rezaei-Abhari, & Danesh, 2013), mentioned that the second stage of labor length was unaffected by applying a warm towel to the perineal area. This result contradicts the findings of (Foroughipour, Firuzeh, & Ghahiri, 2016) once more. They demonstrated that, in terms of the second stage's duration, no significant difference between the hands-on and hands-off groups was present. Moreover, conversely to the current study's findings, (Ismail and Tayel, 2019), stated that the second stage's duration had not significantly differ between the hands-off and hands-on groups. As well as the objection also from (Rahimikian, Talebi, Tehrani, & Mehran, 2015), their results disclosed that the first and second stages' lengths did not significantly differ between the experimental (hand-off technique) and control (hand-on technique) groups, according to their findings. As seen by the researchers, the discrepancy may be due to difference of the used techniques at the present study and the other ones. In addition, this variation can be caused by the various study sample sizes and its selection criteria.

Additionally, it was evident from the current study that the study group required less pain relief during labor than the control group, with a statistically

significant difference between the two groups. This finding match with (Gaheen and Abo Hatab, 2021), when comparing the three intervention groups to the control group, they discovered a statistically significant decline in the percentage of women who need pain relief. (Abdel Monem et al., 2020), also summarized that warm compresses and hands-on groups during the second stage of labor did not require pain treatment. From the researchers' point of view, the reason why the results of the present study and those of earlier studies correspond could be due to the similarity between them regarding the use of warm compress and hands on technique to relieve perineal pain. Also, because of the demographic similarity.

In relation to maternal and newborn outcomes among the studied parturient women, the percentage of women who experienced maternal and newborn complications decreased significantly among the studied women receiving the care bundle compared to the control groups receiving the routine hospital care. Furthermore, absence of statistically significant difference between the study and control groups' mean newborn birth weight (kg) and mean Apgar score at first minute, both of which were within the normal range. While, a difference that was statistically significant was found between the two groups regarding the study group's mean Apgar score at the fifth minute which was higher compared to the control group's. These study findings are in line with (El-Sayed et al. 2022), who reported that there was no significant difference in neonatal birth weight between the studied groups and neonatal Apgar scores at 1st minute. These findings also consistent with (Goh,Tan, Shan Hong, Sulaiman, & Omar, 2021), They concluded that the intervention groups' mean newborn weight and Apgar score fell within the typical range.

Concerning perineal outcomes after vaginal birth, the care bundle application among the study group caused a significant rise in the intact perineum and lowered the risk for episiotomy compared to the routine hospital care among the control group where the majority of them underwent episiotomy. Interestingly, there was a decrease in the percentage of perineal trauma among the care bundle women in contrast to the routine hospital control group where the difference is statistically significant regarding the presence of perineal trauma. These results are consistent with (Abdel Monem, El-Habashy & Yonis, 2020), who established that warm perineal compresses and hands-on during vaginal birth and found to be highly significantly linked to intact perineum and the performance of fewer episiotomies. One meta-analysis was completed by (Magoga et al., 2019), also revealed that the utilization of perineal warm compresses during the second stage of labor

reduces the episiotomy risk. (Modoor, Fouly & Rawas, 2021), also agreed partly with the present results, clarifying that the perineum intactness was better to the control group in the experimental group. Remarkably, fewer participants in the experimental group underwent episiotomy than in the control group. Again, (Sarhan et al., 2022), According to the study, the warm compresses group had a considerably lower prevalence of episiotomy than the control group. Moreover, the present study results are also similar to (Gaheen and Abo Hatab, 2021), they discovered that the three intervention groups' percentage of tears was much lower than that of the control group who had an evident increase of perineal tear. Additionally, in accordance with (El-Sayed et al., 2022) s' findings. In addition, according to (Mohamed, 2016), hands on technique help to prevent perineal tears through supporting the perineum at birth and keeping the fetal head from gradually extending.

At the same context, the present study findings are comparable to (Aasheim, Nilsen, Reinart & Lukasse, 2017; Christine, Lau & Biro, 2020), they demonstrated that using perineal supportive techniques via the second stage of labor can help lower the perineal trauma risk. Also, (Antonakou, 2017; Leenskjoeld, Hoj & Pirhonen, 2015), mentioned that hands-on manual perineal protection at birth could considerably lower the incidence of perineal trauma.

Fortunately, (Basu, Smith & Edwards, 2016) started a quality improvement project in the UK that uses a number of strategies to lower the third- and fourth-degree tears rate. These measures were all referred to as STOMP (Stop Traumatic OASIS Morbidity Project). Women advised to refrain from the urge to push during crowning, applying one hand to the perineum by the clinician and promote birthing positions other than the position with semi-recumbent, as well as informing the woman and the clinicians about potential long-term implications of the third and fourth degree perineal tears. They reported that STOMP is a straightforward and inexpensive set of actions that has significantly reduced the prevalence as regard to the third and fourth degree tears. Moreover, the implementation of OASI Care Bundle project, this considerably decreased the third and fourth degree risk rates of perineal trauma. These measures included prenatal teaching, manual perineal protection, mediolateral episiotomy when essential, and systemic per vaginal and rectal inspection to screen for anal sphincter injury (Gurol-Urganci, et al., 2021). Within the same framework (Bidwell et al., 2021) in a study concerning the experiences of women of the OASI Care Bundle to reduce severe perineal trauma, highlighted the urgent need for the best possible distribution of trustworthy, up-to-date, and thorough educational materials about perineal

trauma.

The researchers believe that the similarity between the results of the earlier research studies and the current study can be assigned to the effect of care bundle application. The first intervention is antenatal information, which was given to woman at the third trimester with a specifically designed printed handout/ pamphlet regarding perineal trauma and care bundle prior to birth to be informed about her maternity care. Whereas, the second intervention is hand-on technique that reduces perineal tension through supporting the perineum during the fetal head crowning and controlling its delivery speed by preserving its flexion and delaying its expulsion through the perineal structures, shielding the anterior and posterior perineal regions by using the right hand for shoulders delivery and body rest during crowning. (Goma, Khedr, & Gouda, 2020; Okeahialam, Sultan, & Thakar, 2024). The third intervention illustrated because the baby's head stretches the perineal tissues, and using warm compress to the perineum might lessen the severity of tearing. (Healy et al., 2020). The reason for this could be that the warm compresses approach relaxes the perineum, promoting smoothly presenting part descent with the result of less using of fundal pressure that can be protective factors against severe perineal trauma (Balachandran, Wong, & Thaka, 2022).

In addition, the fourth intervention is vaginal and rectal examination for tears after birth even with intact perineum is very essential after delivery for early repair and prevention of postpartum hemorrhage. In accordance, studies show that systematic perineal examination following vaginal birth should include anal sphincter assessment, which is necessary to diagnose the existence of perineal trauma. Worryingly, undiagnosed women with perineal trauma or tears are more likely to experience anal incontinence effects and rectovaginal fistula (Bidwell et al., 2021); Hannah and Webb, 2020; Lee et al., 2024; Ryan, McGrinder & Smith, 2024)

Whereas these findings disagree with (Pergialiotis et al., 2022), who discovered that no evidence in the favor of hands on or hands off techniques application. Likewise, (Hannah and Webb, 2020) claimed that there was no evidence that hand manoeuvres may lessen perineal damage. Again, (Wang, Jayasekara & Warland, 2022) also found that the hands-on group had slightly higher episiotomy prevalence in comparison the control group. Regrettably, (lee et al., 2024), midwives, declared that the serious perineal trauma risks in women who gave delivery without assistance was not significantly decreased by the Women Healthcare Australia bundle. From the researchers' perspective, this discrepancy between the results of

the current study and those of prior studies may be caused by difference in study sample size or difference in the inclusion criteria as well as it might be due to the variation in the perineal supportive techniques that were used.

As regard to the degree of perineal tears, the bundle care application group in the current study experienced the first- and second-degree perineal tear among less than one tenth of them. Meanwhile, the first-, second-, third- and fourth-degree perineal tears were reported among less than half of the routine hospital group.

These results partially concur with those of (El-Sayed et al., 2022), who found that the control group had a higher incidence of lacerations in the perineum of all degrees, particularly third- and fourth-degree tears, as opposed to just the perineal first- and second-degree tears among the perineal massage and warm compression groups. At the same line, (Sarhan et al., 2022) illustrated that perineal third- and fourth-degree tears were less common among the perineal warm compresses group than in the perineal massage and control groups.

The current findings also, corresponds with (Abdel Monem, El-Habashy & Yonis, 2020); Aasheim et al., Cochrane review 2017), they revealed that warm compresses application to the perineum after vaginal delivery may decrease the perineal third- and fourth-degree tears, according to moderate-quality evidence. In the same line, (Modoor, Fouly & Rawas 2021), mentioned that primipara women's third- and fourth-degree perineal tears decreased with warm compresses application and (Aasheim et al., 2017), also discovered that applying warm compresses can help reduce severe perineal trauma such as tears of the third or fourth degree.

In addition, a retrospective interventional study, and a prospective cohort study, illustrated that the third and fourth degree tears risks were considerably decreased through manual perineal protection during vaginal birth. (Limbeek, Davis, Currie, & Wong 2022; Meutter, Heesewijk, Woerd-Elting & Leeuw, 2018; Naidu, Sultan & Thakar, 2017) found that third or fourth degree tears were less likely to occur in the hands-on group. Again, (Ferreira-Couto & Fernandes-Carneiro, 2017), concluded that the study group's third and fourth degree lacerations were considerably reduced by the use of perineal warm packs in comparison to women in the control group. Moreover, two old studies the first one surveyed eight trials involving explored that warm compresses were very beneficial in reducing the perineal tears of third- and fourth-degree. In addition, the other study by (Rezaei, Saatsaz, Chan, & Nia, 2014), gave the same conclusion.

From the researchers' standpoint, this agreement between all these studies and the finding of the

current study indicates that hands on and warm compress technique are easy and affordable interventions that should be included for the women 'care during the second stage of labor. Also, this correspondence between the study results could be justified by the impact of hands on technique for manual perineal protection that reduces the risk of a perineal laceration by exerting pressure on the fetal head, which hinders its capacity to push and extend from the pubic arch to the perineum. (Martínez et al., 2021). Along with the hands on technique included in the care bundle of the current study, is the warm compresses application to the perineum during the second stage of labor, which can reduce the likelihood of the third- and fourth-degree perineal tears and, to some extent, prevent spontaneous tears and the necessity for episiotomy in nulliparous women. (Martínez et al., 2021).

Regarding the perineal pain intensity, a reduction in perineal pain intensity that is statistically significant was reported immediately after care bundle application through the second stage of labor among the study group with only few percent of them had severe pain compared to the control group, with more than one third of the control group suffered from severe pain ($P=0.0001^*$). Also, perineal pain intensity still lowered among the study group in the third stage of labor following placenta delivery, with a statistically significant difference between the two groups ($P= 0.012^*$). According to, (Türkmen, Çetinkaya, Apay, Karamüftüoğlu & Kılıç, 2021) randomized clinical trial study, they declared that using warm compresses on the perineum area during the second stage of labor is linked to decreased perineal pain which is compatible with the current study results. Also, (Gaheen and Abo Hatab, 2021), discovered that, 15 minutes after perineal supportive techniques application, there was a noticeable reduction in perineal pain in all three intervention groups when compared to the control group. A third of the control group reported having extremely severe perineal pain, whereas none of the intervention groups did, and there was a statistically significant difference between the four groups. The same line, (Vaziri et al., 2014), they arrived at that a significant decrease of perineal pain severity during the second stage of labor was found among perineal warm compresses group than the control group.

(El-Sayed et al., 2022), also affirmed in their research study that using perineal warm compresses during the second stage of labor can decrease the perineal pain. Moreover, a **randomized controlled trial** portrayed that there was less perineal pain among parturient women after hands on technique from 24 hours to 10 days after delivery. (Martínez et al., 2021) Likewise, another randomized controlled trial conducted by (Modoor, Fouly &

Rawas 2021), emphasized a statistically significant difference regarding perineal pain intensity after birth in comparison to the control and intervention groups.

According to the researchers' point of view, the similarities between the previous studies and the results of the current study has been explained within the literature that warm compress cause; vasodilation, increased blood flow supply to the affected or inflamed perineal tissues that increasing collagen elasticity with tissue flexibility, enhanced muscle stretch and relaxation, which helped parturient women feel more comfortable and less pain transmitted through nociceptive stimulation. (**Ozgoli, Mobarakabadi, Heshmat, Majd, & Sheikhan, 2016**).

While, (**Thomas & Jayabharathi, 2016**), illustrated that, the hands-off and hands-on groups experienced significantly different levels of perineal pain. The parturient women in the hands-off group experienced less perineal pain compared to the hands-on group. According to the researchers outlook view, this discrepancy between the results of this study and the current study may be caused by difference in the demographic characteristics or in the inclusion criteria among subjects of both studies.

In maternity services, the implementation of quality improvement initiatives as care bundle has the potential to significantly lower the risks of perineal trauma. To enable a worldwide consensus about perineal trauma prevention in maternity services, further researches should be conducted to keep expanding on the strengths and applications of these interventions.

Conclusion: The nursing care bundle implementation comprising evidence-based interventions performed collectively was effective in reducing perineal trauma and pain as well as improving birth outcomes.

Recommendations: In the light of the existing findings, the following recommendations are suggested;

The nursing care bundle application should be included in all nursing education and ongoing in-service training programs for maternity nurses.

The implementation of nursing care bundle should be considered as a part of the routine hospital care during vaginal birth.

Application of the nursing care bundle on larger sample.

References:

Aasheim, V., Nilsen, A., Reinart, L., & Lukasse, M., (2017). Perineal techniques during the second stage of labour for reducing perineal trauma, *The Cochrane database of systematic reviews*, 6(6), 1-3. Doi: 10.1002/14651858.CD006672.

Abd-Ella, N., Kandeel, H., & Gouda, A., (2021). Effect of late pregnancy self-perineal massage on

the perineal state of the primiparurients. *Tanta Scientific Nursing Journal*, 23 (4), 52-73. Doi: 10.21608/tsnj. 2021.208493.

Abdel Monem, A., El-Habashy, M., & Yonis, S. (2020). Effect of hands-on, hands-off and warm compresses perineal techniques during the 2nd stage of labor on perineal outcomes among primipara with vaginal delivery. *International Journal of Novel Research in Healthcare and Nursing*, 7(3), 609-624. Retrieved from <https://www.noveltyjournals.com> > upload >

Aguiar, M., Farley, A., Hope, L., Amin, A., Shah,P., Manaseki-Holand, S. (2019). Birth-related perineal trauma in low- and middle-income countries: a systematic review and meta-analysis. *Maternal and Child Health Journal*, 23 (8): 1048–1070. Doi: 10.1007/s10995-019-02732-5.

Antonakou, A. (2017). Hands-on or hands-off the perineum at childbirth: A re-appraisal of the available evidence. *The European Journal of Midwifery*, 1(10), 1-3. DOI: <https://doi.org/10.18332/ejm/78588>.

Aquino, C., Guida, M., Saccone, G., Cruz, Y., Vitagliano, A., Zullo,F., & Berghella ,V. (2020). Perineal massage during labor: a systematic review and meta-analysis of randomized controlled trials. *The Journal of Maternal-Fetal & Neonatal Medicine*, 33(6), 1051-1063. Doi: 10.1080/14767058.2018.1512574.

Balachandran, A., Wong, K., & Thakar, R. (2022). Risk factors for and management of obstetric anal sphincter injury, *Obstetrics, Gynaecology and Reproductive Medicine*, 32(6), 105-109.DOI:10.1016/j.ogrm.2019.01.012.

Basu, M., Smith, D.,& Edwards, R. (2016). Can the incidence of obstetric anal sphincter injury be reduced? The STOMP experience, *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 202(1), 55-59. Doi: 10.1016/j.ejogrb. 2016. 04.033.

Bidwell, P., Sevdalis, N., Silverton, L., Harris, J., Gurol-Urganci, I., Hellyer, A., Freeman, R., Meulen, J., & Thakar,R. (2021) .Women's experiences of the OASI care bundle; a package of care to reduce severe perineal trauma. *International Urogynecology Journal*, 32(7), 1807-1816. Doi: 10.1007/s00192-020-04653-2.

Bidwell,P., Sevdalis,N., Silverton,L., Harris,J., Gurol-Urganci,I., Hellyer,A., Freeman,R., Meulen,JV., & Thakar,R., (2021). Women's experiences of the OASI Care Bundle; a package of care to reduce severe perineal trauma, *International urogynecology journal*, 32(7), 1807-1816. Doi: 10.1007/s00192-020-04653-2.

Bidwell, P., Thakar, R., Gurol-Urganci, I., Harris, J., Silverton, L., Hellyer, A., Freeman, R., Morris, E., Novis,V.,& Sevdalis,N. (2020). Exploring clinicians' perspectives on the 'obstetric anal sphincter injury care bundle' national quality

- improvement programme: a qualitative study. *British medical journal Open*, 10(9), 1-10. Doi: 10.1136/bmjopen-2019-035674.
- Bidwell, P., Thakar, R., Sevdalis, N., Silverton, L., Novis, V., Hellyer, A., Kelsey, M., Meulen, J., & Gurol-Urganci, I. (2018).** A multi-centre quality improvement project to reduce the rate of obstetric anal sphincter injury (OASI): study protocol. *BMC Pregnancy and Childbirth*, 18(331), 2-11. DOI:10.1186/s12884-018-1965-0.
- Bulchandani, S., Watts, E., Sucharitha, A., Yates, D., & Ismail, K. M. (2015).** Manual perineal support at the time of childbirth: a systematic review and meta-analysis. *BJOG: An International Journal of Obstetrics & Gynaecology*, 122(9), 1157-1165. Doi: 10.1111/1471-0528.13431.
- Christine. E., Lau, R., & Biro, M. A. (2020).** Midwives' and doctors' perceptions of their preparation for and practice in managing the perineum in the second stage of labor: A cross-sectional survey. *Midwifery Journal*, 31(1), 122-131. Doi: 10.1016/j.midw.2014.07.002.
- Committee on Practice Bulletins-Obstetrics, (2018),** ACOG Practice Bulletin No. 198, Prevention and management of obstetric lacerations at vaginal delivery, *Obstetrics and gynecology*, 132(3), 87-102. DOI:10.1097/AOG.0000000000002841.
- Dawson, B D., and Trapp, R G. (2001).** Reading the medical literature: Basic & Clinical Biostatistics. Lange Medical Book/ McGraw – Hill. Medical Publication Division, New York. 3rd ed., PP 161-218 and Ch. 13, PP 305-314, 2001.
- Delgado, DA., Lambert, BS., Boutris, N., McCulloch, PC., Robbins, AB., Moreno, MR., Moreno, MR., & Harris, JD. (2018).** Validation of digital visual analog scale pain scoring with a traditional paper-based visual analog scale in adults. *Journal of the American Academy of Orthopaedic Surgeons. Global research & reviews*. 2(3).1-6. Doi: 10.5435/JAAOSGlobal-D-17-000 88.
- Downie WW, Leatham PA, Rhind VM, Wright V, Branco JA, & Anderson JA. (1978),** *Studies with pain rating scales. Annals of the rheumatic diseases*, 37(4), 378-381. Doi:10.1136/ard.37.4.378.
- El-Sayed, M., Lashin, M., Mohammed, A., & Abo El-Fath , A. (2022).** Perineal management techniques to reduce perineal trauma during the second stage of labor. *The Egyptian Journal of Hospital Medicine*, 89(1), 4640-4644. DOI: 10.21608/ejhm. 2022.259128.
- Fahami, F., Shokoohi, Z., Kianpour, M., Norbakhsh, V., & Heidari, T. (2011).** The effects of perineal management techniques on labor complications, *Iranian journal of nursing and midwifery research*, 17(1), 52-57.
- Ferraz MB, Quaresma MR, Aquino LR, Atra E, Tugwell P, Goldsmith CH. (1990).** Reliability of pain scales in the assessment of literate and illiterate patients with rheumatoid arthritis. *The Journal of rheumatology*, 17(8), 1022-4.
- Ferreira-Couto, CM., & Fernandes-Carneiro, MDN. (2017).** Trauma perineal prevention: an integrative literature review, *Enfermería Global Journal*, 16(47), 564-574. Doi.org/10.6018/eglobal.16.3.25213 1.
- Foroughipour, A., Firuzeh, F., & Ghahiri, A. (2016).** The effect of perineal control with hands-on and hand-poised methods on perineal trauma and delivery outcomes. *Journal of Research Medical Sciences*, 16 (8), 1040– 1046.
- Gaheen, M., & Abo-Hatab, T., (2021).** Effect of utilizing perineal massage, warm compresses and hands on techniques during the second stage of labor on perineal outcomes. *Tanta Scientific Nursing Journal*, 23(4), 36-60. DOI:10.21608/tsnj. 2021.210228.
- Gallagher EJ, Bijur PE, Latimer C, Silver W. (2002).** Reliability and validity of a visual analog scale for acute abdominal pain in the ED. *The American Journal of Emergency Medicine*, 20(4), 287-290. Doi: 10.1053/ajem. 2002. 33778.
- Ganji, Z., Shirvani, M., Rezaei-Abhari, F., and Danesh, M. (2013).** The effect of intermittent local heat and cold on labor pain and child birth outcomes, *Iranian journal of nursing and midwifery research*, 2013, 18(4):298-303.
- Gilhooly, D., Green, SA., McCann, C., Black, N., & Moonesinghe, SR., (2019).** Barriers and facilitators to the successful development, implementation and evaluation of care bundles in acute care in hospital: a scoping review. *Implementation Science Journal*, 14(1), 3-12 Doi:10.1186/s13012-019-0894-2.
- Goh, YP., Tan, PC., Shan Hong, JG., Sulaiman, S., and Omar SZ. (2021)** Combined massage and warm compress to the perineum during active second stage of labor in nulliparas, A randomized trial. *International Journal of Gynecological Obstetric*, 155 (3), 532-538. Doi: 10.1002/ijgo.13613.
- Goma, L., Khedr, N., & Gouda A. (2020).** Effect of utilizing hands-on versus off method during delivery of fetal head on occurrence of perineal tear, *Mansoura Nursing Journal*, 7(2), 136-152. DOI:10.15640/ijn.v7n2a7.
- Gurol-Urganci, I., Bidwell, P., Sevdalis, N., Silverton, L., Novis, V., Hellyer, A., Freeman, R., Meulen, J., & Thakar, R., (2021).** Impact of a quality improvement project to reduce the rate of obstetric anal sphincter injury: a multicentre study with a stepped-wedge design. *an international journal of obstetrics and gynaecology*, 128(3), 584-592. Doi: 10.1111/1471-0528.16396.

- Hannah, G., D., Webb, S. (2020).** The OASI Care Bundle—a lively topic for discussion. *MIDIRS Midwifery Digest Journal*, 30(4), 414-417.
- Healy, M., Nyman, V., Spence, D., Otten, R. & Verhoeven C. (2020),** How do midwives facilitate women to give birth during physiological 2nd Stage of labor? a systematic review. *PLOS ONE Journal*, 15(7), 1-19. Doi:10.1371/journal.pone.0226 502.
- Ibrahim, H., Elgzar, W., & Hassan, H. (2017).** Effect of warm compresses versus lubricated massage during the second stage of labor on perineal outcomes among primiparous women. *IOSR Journal of Nursing and Health Science*, 6(4);64-76. DOI: 10.9790/1959-0604056476.
- Institute for Healthcare Improvement. (2012).** Using care bundles to improve health cre quality. IHI Innovation Series white paper. Cambridge, Massachusetts: Retrieved from https://www.urotoday.com/images/catheters/pdf/IHI_Using_Care_Bundles_WhitePaper2012.pdf
- Ismail, N., & Tayel, A . (2019).** Effect of hands-off versus hands-on maneuver during the second stage of labor on birth outcomes among primiparae women, *IOSR Journal of Nursing and Health Science* ,8(4), 43-54. DOI: 10.9790/1959-0804054354.
- Jansson, M.H., Franzén, K., Hiyoshi, A., Tegerstedt, G., Dahlgren, H., & Nilsson, K., (2020).**Risk factors for perineal and vaginal tears in primiparous women - the prospective POPRACT-cohort Study, *BMC Pregnancy Childbirth*,20(749),2-14. Doi: 10.1186/ s12884-020-03447-0.
- Jurczuk, M., Bidwell, P., Gurol-Urganci, I., Meulen, J., Sevdalis,N., Silverton, L., & Thakar,R. (2021).** The OASI care bundle quality improvement project: lessons learned and future direction. *International urogynecology journal*, 32(7), 1989-1995. Doi:10.1007/s00192-021-0478 6-y.
- Jurczuk, M., Bidwell, P., Martinez, D., Silverton, L., van der Meulen, J., Daniel Wolstenholme,D., Thakar,R., Gurol-Urganci, I., & Sevdalis,N. (2021)** .OASI2: a cluster randomised hybrid evaluation of strategies for sustainable implementation of the obstetric anal sphincter injury care bundle in maternity units in great britain – Study Protocol. *Implementation science*, 16(1), 55. Doi: 10.1186/s13012-021-01125-z.
- Kleprlikova, H., Kališ V., Lucovnik, M., Rusavy,Z., Blaganje,M., Thakar,R. & Ismail,KM. (2020)** Manual perineal protection: The know-how and the know-why. *Acta obstetricia et gynecologica Scandinavica*, 99(1), 445–450. Doi:10.1111/ aogs.13781.
- Lavallée, J., Gray, T., Dumville, Jo., Russell, W., & Cullum N.,(2017)** The effects of care bundles on patient outcomes: a systematic review and meta-analysis. *Implementation Science Journal*, 12(1), 2-13. Doi: 10.1186/s13012-017-067 0-0.
- Lee,N., Allen,J., Jenkinson,B., Hurst,C., Gao,Y.,&Kildea,S.,(2024),** A pre-post implementation study of a care bundle to reduce perineal trauma in unassisted births conducted by midwives, *Women and birth journal*, 37(1),159-165. Doi: 10.1016/j. wombi.2023.08.003.
- Leenskjoeld,S., Hoj, L., & Pirhonen,J. (2015).** Manual protection of the perineum reduces the risk of obstetric anal sphincter ruptures, *Danish medical journal*, 62(5), 1-5.
- Limbeek,S., Davis,D., Currie,M., Wong, N. (2022).** Non-surgical intrapartum practices for the prevention of severe perineal trauma a systematic review protocol, *JBI database of systematic reviews and implementation reports Journal*, 14(4), 30-40. Doi:10.11124/ JBIS RIR-2016-2473.
- Magoga, G., Saccone, G., Al-Kouatly, H., Dahlen, H., Thornton, Ch. & Akbarzadeh, M., Ozcan,T., & Berghella, V. (2019).** Warm perineal compresses during the 2nd stage of labor for reducing perineal trauma: A meta-analysis. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 240(1), 93–98. Doi: 10.1016/j.ejogrb. 2019. 06.011.
- Martínez,E., Sáez,Z., Sánchez, E., Ávila,M., Conesa,E.,& Ferrer,M. (2021),** Perineal protection methods: knowledge and use, *Revista da Escola de Enfermagem da USP Journal*, 55(1),1-8. Doi.10.1590/ 1980-220X-REEUSP-2020-0193.
- Meutter, L., Heesewijk, A., Woerd-Eltink, L. & Leeuw J. (2018).** Implementation of a perineal support programme for reduction of the incidence of obstetric anal sphincter injuries and the effect of non-compliance. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 230 (1), 119-123. Doi: 10.1016/j.ejogrb.2018.09.021.
- Modoor,S., Fouly,H., & Rawas,H.(2021).** The effect of warm compresses on perineal tear and pain intensity during the second stage of labor: A randomized controlled trial, *Belitung nursing journal*, 7(3), 210-218. Doi: 10.33546/bnj.1452.
- Mohamed, A. (2016).**Risk factors for birth related perineal trauma among low risk parturient women and nursing implications. *IOSR Journal of Nursing and Health Science*, 5(1), 40-48. DOI: 10.9790/1959-05114048.
- Mohamed,S., Abd Ella, N., Hassan, M., & Khedr, N., (2017).** Practices that applied on protection of perineal trauma among parturient women. *IOSR Journal of Nursing and Health Science (IOSR-JNHS)*, 6 (5), 88-95. Doi: 10.9790/ 1959-0605098895).
- Naidu, M., Sultan, A H., & Thakar, R. (2017)** Reducing obstetric anal sphincter injuries using perineal support: our preliminary experience. *International urogynecology journal*, 28(3), 381–389. Doi: 10.1007/s00192-016-3176-4.

- National Institute for Health and Clinical Excellence. (2017).** Intrapartum care: care of healthy women and their babies during childbirth. NICE clinical guideline [CG190]. London: NICE.
- Okeahialam, N., Sultan, A., & Thakar, R.,(2024).**The prevention of perineal trauma during vaginal birth, *American journal of obstetrics and gynecology*, 230(3),991-1004.Doi:10.1016/j.ajog.2022.06.021.
- Ozgoli, G., Mobarakabadi, S. S., Heshmat, R., Majd, H. A., & Sheikhan, Z. (2016).** Effect of LI4 and BL32 acupressure on labor pain and delivery outcome in the first stage of labor in primiparous women: A randomized controlled trial. *Complementary Therapies in Medicine Journal*, 29(1), 175-180. Doi.org/ 10.1016/ j.ctim.2016.10.009.
- Pergialiotis, V., Bellos, I., Fanaki, M., Vrachnis, N., & Doumouchtsis, S.(2020).** Risk factors for severe perineal trauma during childbirth: An updated meta-analysis, *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 247(5), 94-100.DOI:10.1016/j.ejogrb. 2020 .02.025.
- Persson, M., Lindberg, I., & Öhman, A., (2023).** Regional and clinical guidelines for prevention and care of obstetric anal sphincter injuries -A critical frame analysis. *Midwifery Journal*, 119(1), 1-7, Doi: 10.1016/ j.midw.2023.103608.
- Rahimikian, F., Talebi, F., Tehrani, S., & Mehran, A. (2015).** Comparing the effect of active and expectant managements of the second stage of labor on perineal status. *Hormozgan Medical Journal*, 19(3), 154-159.
- Resar R., Griffin F.A., Haraden C., & Nolan TW. (2012).** Using care bundles to improve health care quality. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; (Available on www.IHI.org).
- Rezaei, R., Saatsaz, S., Chan, Y. H., & Nia, H. S. (2020).** A comparison of the “hands-off” and “hands-on” methods to reduce perineal lacerations: a randomised clinical trial. *The Journal of Obstetrics and Gynecology of India*, 64(6), 425-429. Doi: 10.1007/s13224-014-0535-2.
- Roper, JC., Amber, N., Wan, OYK., Sultan, AH., & Thakar R. (2020).** Review of available national guidelines for obstetric anal sphincter injury, *International urogynecology journal*, 31(11), 2247–2259. Doi: 10.1007/s00192-020-04464-5.
- Royal College of Obstetricians and Gynaecologists. (2018).** OASI care bundle project team: Implementation guide for maternity sites in the roll-out phase 2017-2018. RCOG London. Retrieved from <https://www.rcog.org.uk › media › rntlozz3 › oa...>
- Royal College of Obstetricians & Gynaecologists, Royal College of Midwives: (2016).** New joint initiative to prevent severe tearing during childbirth. London.
- Royal College of Obstetricians and Gynaecologists. (2015).** The management of third- and fourth-degree perineal tears. Green-top guideline. Retrieved from <https://www.rcog.org.uk/media/5jeb5hzu/gtg-29.pdf>.
- Ryan, T., McGrinder, T., & Smith, V. (2024).** Care bundles for women during pregnancy, labour/birth, and postpartum: a scoping review [version 1; peer review: awaiting peer review], *HRB Open Research Journal*, 40(1), 1-17. Doi.org/10.12688/hrbo.penres.13905.1.
- Sarhan, E., Kassem, I., Gamal, A., & Khalil, A. (2022).** Effect of warm compresses versus lubricated massage during the second stage of labor on perineal integrity among primiparous women, *Menoufia Nursing Journal Faculty of Nursing Menoufia University*, 7(1), 111-135. DOI:10.21608/menj.2022.227543.
- Sultan AH. (1999).** Editorial: Obstetrical Perineal Injury and Anal Incontinence. *Clin Risk*, 5(6), 193-196. Doi.org/10.1177/ 13562 6229900 500601.
- Thomas, P. & Jayabharathi, B. (2016).** Effectiveness of hands-off versus hands -on techniques on perineal trauma and perineal pain among parturient mothers. *Asian Journal of Pharmaceutical and Clinical Research*, 9(6), 179-183. DOI:10.22159/ajp cr.2016.v9i6.14045.
- Türkmen, H., Çetinkaya, S., Apay, E., Karamüftüoğlu, D., & Kılıç, H. (2021).** The effect of perineal warm application on perineal pain, perineal integrity, and postpartum comfort in the 2nd stage of labor: Randomized Clinical Trial. *Complementary Medical Research Journal*, 28(1):23-30. Doi: 10.1159/000507605.
- Vaziri, F., & Farahmand, M. Samsami ,S., Forouhari, M., Hadianfard, M., & Sayadi, M. (2014).** The effects of warm perineum compress during the second phase of labor on first- birth outcomes, *Modern Care Journal*. Retrieved from <https://www.semanticscholar.org/paper/The-effects-of-warm-perineum-compress-during-the-of-Vaziri-Farahmand/4fc0bd79a205dc5f7977b4c14a8dc14cc3d06744>
- Wang, H., Jayasekara, R., & Warland, J. (2022).** The effect of “hands on” techniques on obstetric perineal laceration: A structured review of the literature. *Women and Birth Journal*, 28(3), 194-198. Doi: 10.1016/j.wombi.2015.02.006.
- Women’s Healthcare Australasia. (2019).** The how to guide: WHA CEC Perineal protection bundle©. Retrieved from [https:// women.wcha.asn.au/collaborative/intervention-bundle](https://women.wcha.asn.au/collaborative/intervention-bundle).