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| Type of Policy: PATIENT CARE | Category: PROVISIONS OF CARE, TREATMENT, AND SERVICES (PC) |
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| Title: <i>Placement of Uterine Tamponade Balloon Catheter or Jada Catheter System for Postpartum Hemorrhage</i> | Policy #: 2372 |
| Page: 1 of 4 | Replaces #: Women's Services Process 1263-2525 |
| Issue Date: 11/23 | Developed By: Women's Services Policy and Procedure Committee |
| Revision Dates: | Approved By: Patient Care Executive <i>KEdmondson MSN, RN, NEA-BC</i> |

I. PURPOSE:

This policy provides a guide for nurses to assist physicians with the placement of a uterine tamponade balloon catheter or Jada catheter system for postpartum hemorrhage (PPH) and monitoring requirements by the qualified Registered Nurse (RN).

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

- A. Uterine Tamponade Balloon Catheter - a catheter used to control post-partum uterine bleeding from placental-site and lower uterine segment. Uterine tamponade balloon catheter may be placed transvaginally after a vaginal delivery or transabdominally during a cesarean birth.
- B. Jada Catheter System - is an intrauterine catheter system, that once in place, it requires to be connected to suction to create a vacuum inside the uterus to control postpartum hemorrhage. Used for rapid treatment of PPH related to uterine atony when non-invasive treatment fails. It induces a uterine contraction after placement and connection to a low suction source.
- C. Obstetrical provider - Obstetrics/Gynecologist (OB/GYN) physician.
- D. Qualified registered nurse – a licensed registered nurse that has completed unit specific competencies to care for mothers and newborns or is under the direct supervision of a qualified registered nurse.

III. POLICY:

It is the policy of Orlando Health that:

- A. The obstetrical provider must explain procedure to the patient.
- B. The obstetrical provider shall insert the uterine tamponade balloon catheter or Jada catheter.
- C. The uterine tamponade balloon catheters and Jada catheter system should not be a substitute for surgical management and fluid resuscitation of life-threatening postpartum hemorrhage.

IV. PROCEDURE:

- A. Indications to placing uterine tamponade balloon catheter or Jada catheter system:
 - 1. The obstetrical provider evaluates patient for lacerations, retained products of conception, or other causes of bleeding by removing clots and
 - 2. There is no response to primary uterotonic drugs (Oxytocin-Pitocin) or
 - 3. Use in conjunction with secondary uterotonics: (Methylergonovine- Methergine, Carboprost-Hemabate, and/or Misoprostol- Cytotec).
- B. The obstetrical provider can repair vaginal and external genital lacerations with the uterine tamponade balloon catheter or Jada catheter system in place.
- C. Insert Foley Catheter prior to procedure if not already in place to facilitate palpation and contraction of the uterus.
- D. The use of the uterine tamponade balloon catheter or Jada catheter system is contraindicated in the presence of:

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1. Pregnancy
2. Retained placenta products
3. Purulent infections of the vagina, cervix, or uterus
4. Arterial bleeding requiring surgical exploration or embolization
5. Disseminated intravascular coagulation (DIC)
6. Untreated uterine anomaly
7. Cervical cancer
8. Unresolved uterine inversion
9. Untreated uterine rupture
10. Other contraindications for Jada catheter system placement:
 - a. Before use of the Jada catheter in C-Sections: the cervix must be less than (<) three (3) cm dilated
 - b. Uterus less than (<) 34 weeks
 - c. More than 48 hours post-delivery
 - d. Cervix is less than or equal to (≤) 2-3 cm dilated
 - e. Presence of clots in the uterus
 - f. Etiology of PPH is other than uterine atony
- E. Physician will explain procedure to the patient with purpose, benefits and risks.
- F. Obtain equipment and supplies from postpartum hemorrhage cart or supply room.
- G. Patient Monitoring:
 1. Intrauterine tamponade balloon catheter: patient is managed on strict bedrest in Labor and Delivery/Labor and Delivery PACU or designated unit until 2 hours after the intrauterine balloon catheter is removed.
 2. Jada catheter system - the patient may remain on unit of origin.
 3. No fundal massage will be performed.
 4. IV access will be maintained while intrauterine tamponade balloon catheter or Jada catheter system are in place.
 5. Consider use of epidural analgesia if epidural still in place; otherwise follow pain management per provider's orders.
 6. Monitor and document pulse, blood pressure, oxygen saturation, fundal height, and pain:
 - a. Every 15 minutes x 1 hour
 - b. Every 30 minutes x 1 hour
 - c. Every 1 hour x 4 hours
 - d. Every 4 hours until removal unless otherwise directed
 7. Temperature and respiratory rate: at minimum hourly x 4 then every 4 hours until 24 hours post-procedure.
 8. Assess and document every hour or more frequently as indicated by patient condition:
 - a. Pain level (including cramping/abdominal pain)
 - b. Intake and Output (I & O)

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Title: ***Placement of Uterine Tamponade Balloon Catheter or Jada Catheter System for Postpartum Hemorrhage***

Policy #: **2372**

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Replaces #: Women's Services Process 1263-2525

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KEdmondson MSN, RN, NEA-BC

- c. Blood in drainage bag (for intrauterine tamponade balloon catheter) or suction canister (for Jada catheter system)
- 9. Monitor for signs and symptoms of increased bleeding or patient deterioration and notify provider:
 - a. Increased or unrelieved uterine cramping
 - b. Increasing fundal height
 - c. Tachycardia
 - d. Decreased BP
 - e. Pallor
 - f. Diaphoresis
 - g. Change in LOC
 - h. Bleeding around the device
 - i. More than 200 mL of lochia in intrauterine balloon drainage bag or suction canister
 - j. Urine output less than 120 mL in 4 hours
 - k. Abnormal laboratory results

V. DOCUMENTATION:

- A. Document the insertion and discontinuation of the uterine tamponade balloon catheter or Jada catheter system in Epic, on the Avatar.
- B. Document total volume of sterile saline/water used to fill balloon.
- C. Document number of packing sponges left inside vagina.
- D. If procedure done in the Operating Room after a Cesarean Section, document Procedure in the Delivery Summary-C-Section.

VI. REFERENCES:

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- C. Dabelea, V., Schultze, P., & McDuffie, R. S., 2007, Intrauterine Balloon Tamponade in the Management of Postpartum Hemorrhage. *American Journal of Perinatology*, 24(6), 359-364.
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- E. Cook Medical (2021). Bakri Post-Partum Balloon Instructional Booklet. www.cookmedical.com.
- F. D'Alton ME, Rood KM, Smid MC, et al. Intrauterine vacuum-induced hemorrhage-control device for rapid treatment of postpartum hemorrhage. *Obstet Gynecol*. 2020;136(5):882-891.
- G. Organon LLC. Jada System. © 2022 Organon group of companies. All rights reserved. © 2022 Organon group of companies.

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VII. ATTACHMENTS:

- A. Insertion of the Intrauterine Balloon Catheter for Postpartum Hemorrhage two pages.
- B. Insertion of Jada Catheter System for Postpartum Hemorrhage one page.
- C. Jada Catheter System for PPH Use Algorithm one page

Title: ***Placement of Uterine Tamponade Balloon Catheter or Jada Catheter System for Postpartum Hemorrhage***

Policy #:

***Attachment A – Assisting with Insertion of the Intrauterine Balloon Catheter for Postpartum Hemorrhage
(2 pages)***

A. Insertion:

1. Obtain equipment and supplies from postpartum hemorrhage cart or supply room:
 - a. Pre-packaged kit that contains uterine tamponade balloon catheter
 - b. 60 mL luer-lock syringe
 - c. Sterile Normal saline, sterile water or Lactated Ringers
 - d. Foley catheter
 - e. Urometer drainage bag to attach uterine tamponade balloon catheter
 - f. Betadine (unless PT is allergic)
 - g. X-Ray detectable sponges
 - h. Speculum, long ring forceps
 - i. Sterile gloves
 - j. Ultrasound machine
 - k. X-ray detectable sponges
2. Assist patient to lithotomy position if indicated.
3. Open the sterile equipment and packages after inspecting integrity.
4. Insert Foley Catheter prior to procedure if not already in place to facilitate palpation and contraction of the uterus.
5. Once physician inserts the balloon catheter, provide them with the sterile saline or water prepared in a 60 mL syringe.
6. Record the amount of sterile saline or water given through the stopcock, to fill the tamponade balloon. Volume recommended to inflate the balloon is between 250-300 mL with a maximum of 500 mL.
7. Document accurately instilled volume.
8. Assist with placement of vaginal packing (which provides counter-pressure and maximizes tamponade effect).
9. Assist physician in securing catheter to patient's inner thigh with gentle traction.
10. Connect drainage port to a fluid collection bag (urometer draining bag).
10. Broad spectrum antibiotic prophylaxis may be ordered per provider while balloon is in place.
11. A pen mark on the patient's abdomen may be used to indicate level of fundus upon insertion and could be used to determine if fundal height is increasing over time.
12. The balloon drainage port and tubing may be flushed to clear clots. If there is no drainage and/or the fundus is increasing in height. Flush balloon drainage port and tubing with 15-30 mL sterile normal saline (requires physician's order).

B. Removal of uterine tamponade balloon catheter:

1. Prior to removal of tamponade balloon notify charge nurse.
2. Maximum catheter indwell time is 24 hours.
3. Only the obstetrical provider will deflate and remove the catheter with the assistance of the RN.
4. Remove tension from the balloon catheter tube.
5. The obstetrical provider may remove intrauterine balloon fluid all at once or in incremental volumes (over a period of time) not to exceed 24 hours total from the time of insertion.
6. Verify that the original volume inserted in the balloon was removed (for this information refer in Epic, the Avatar).
7. Remove vaginal packing. Verify and document correct quantity of packing has been removed. Obtain X-Ray if sponge count is incorrect.
8. Once all fluid is removed from the intrauterine balloon, the catheter is withdrawn and discarded per provider.

C. Post Removal Monitoring for intrauterine tamponade balloon catheter:

1. Patient will remain in designated unit for a minimum of 2 hours post intrauterine balloon removal.
2. Monitor patient's pulse, blood pressure, oxygen saturation, vaginal bleeding, and pain. Include fundal assessment with gentle palpation:

Title: ***Placement of Uterine Tamponade Balloon Catheter or Jada Catheter System for Postpartum Hemorrhage***

Policy #:

Attachment A – Assisting with Insertion of the Intrauterine Balloon Catheter for Postpartum Hemorrhage (2 pages)

- a. Every 15 min X 1 hour
- b. Every 30 min X 1 hour
- c. Then postpartum orders
3. Temperature and respiratory rate every four (4) hours.
4. Assess the following per postpartum orders or more frequently if patient condition indicates:
 - a. Pain level including cramping or abdominal pain.
 - b. I &O
 - c. Vaginal bleeding
5. Notify provider if patient's condition deteriorates.

Title: ***Placement of Uterine Tamponade Balloon Catheter or Jada Catheter System for Postpartum Hemorrhage***

Policy #:

Attachment B - Assisting with Insertion of the Jada Catheter System (1 page)

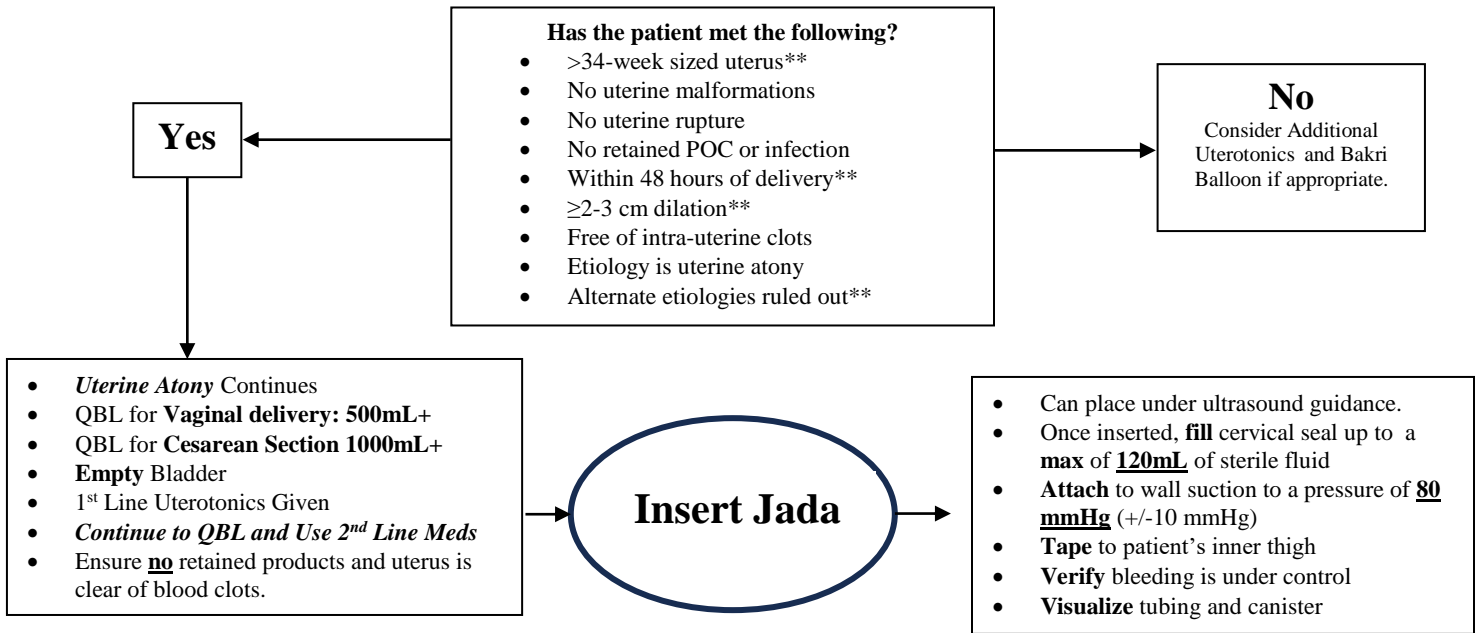
- A. Insertion:
1. Obtain equipment and supplies from postpartum hemorrhage cart or supply room:
 - a. Jada catheter system pre-packaged sterile kit
 - b. Sterile water bottle
 - b. Vacuum canister
 - c. Regulated vacuum source
 - d. Tape
 - e. Ultrasound machine
 2. Precautions: never inflate the Cervical Seal with air to minimize the risk of air embolism if Cervical Seal bursts.
 3. Open sterile equipment and packages after inspecting integrity.
 4. Insert Foley Catheter prior to procedure if not already in place to facilitate palpation and contraction of the uterus.
 5. Connect a vacuum canister and sterile standard vacuum tubing to a regulated vacuum source (suction).
 6. Remove air that is in the Cervical Seal with a sterile luer syringe.
 7. Fill sterile luer syringe with 60 mL of sterile fluid.
 8. Obstetrical provider will confirm through direct visualization that the cervix is greater than or equal to (\geq) 2-3 cm dilated to allow Jada catheter placement.
 9. After insertion of the Jada catheter system per obstetrical provider, attach the 60 mL luer syringe filled with sterile water to fill the Cervical Seal. May need to add 60 mL extra to cover the cervix external os to create a seal for vacuum. Once inserted, the Intrauterine Loop is inside the uterus and the Cervical Seal is within the vagina at the external cervical os.
 10. Document accurately instilled volume.
 11. Connect the Jada catheter system to suction with pressures set at 80 mm of Hg (+/-10 mmHg) as ordered.
 12. Document output to the vacuum canister accurately.
 13. Jada is secured to the patient's inner thigh with tape without applying tension to avoid dislodgement.
 14. Broad spectrum antibiotic prophylaxis may be ordered per provider while balloon is in place.
 15. It is recommended to leave the Jada in place with vacuum applied until:
 - a. PPH/abnormal postpartum uterine bleeding is controlled for at least 1 hour.
 - b. The uterus is firm.
 - c. Patient is stable.
 16. Maximum indwell time is 24 hours, usual indwell time is 1-5 hours.
- B. Removal of Jada catheter system:
1. Only the obstetrical provider will deflate and remove the catheter with the assistance of the RN.
 2. Prior to removal of the Jada, notify charge nurse.
 3. Disconnect vacuum tubing from the Jada catheter while vacuum is still on to collect any blood from the tubing into the canister. Secure the suction tubing in case that the vacuum needs re-application.
 4. Attach a 60 mL luer syringe to remove the fluid from the Cervical Seal and keep the Jada System in place for at least 30 minutes while monitoring for any recurrent uterine bleeding.
 5. Jada is removed if:
 - a. PPH/abnormal postpartum uterine bleeding remains controlled.
 - b. The uterus remains firm for a minimum of 30 minutes after suction is disconnected.
 6. Removal Precautions:
 - a. Do not remove the Jada catheter while vacuum is applied, to avoid uterine inversion. Always disconnect suction catheter from Jada before removal.
 - b. Remove all fluid instilled into the Cervical Seal prior to removing Jada to avoid disruption of the vaginal mucosa or any sutured lacerations.
 7. Post Removal Monitoring:
 - a. Assess fundus and lochia every 15min x1 hour
 - b. Notify Provider if bleeding restarts after removal.

Title: **Placement of Uterine Tamponade Balloon Catheter or Jada Catheter System for Postpartum Hemorrhage**

Policy #:

Attachment C - Jada Catheter System for PPH Use Algorithm (1page)

Jada for PPH Use Algorithm



If BLEEDING CONTINUES, consider treatment failure, and continue with PPH Algorithm
LEAVE VACUUM SYSTEM ON FOR 1 HOUR AFTER BLEEDING IS CONTROLLED AND PATIENT IS STABLE
Max indwell time of 24 hours, Usual Treatment Time 1-5 hours

Jada Removal

- OB Physician**
- **1 hour** since bleeding under control
 - **Disconnect** tubing from Jada
 - **Remove** all fluid from cervical seal
 - **Wait 30 minutes** before removal of device to ensure bleeding does not ensue
 - **Remove** Jada while supporting uterus
 - **Assess** uterine tone and bleeding
 - **Document** in medical record

- Nursing**
- **Assist** Provider with removal
 - **Assess** fundus and lochia q15min x1 hour
 - **Document** removal on LDA
 - **Notify** provider if bleeding ensues after removal

Warnings and Precautions

The following situations have not been appropriately studied when using the JADA system and cannot be endorsed by Organon. They are relative contraindications and JADA placement can be considered with the knowledge of potential complications. Having said that, the decision to place JADA should be made at the provider's discretion using clinical judgment. With the following conditions listed below, there is a potential risk for continued hemorrhage, risk of infection and/or injury to the cervix/uterus.

- >34-week sized uterus**
 Within 48 hours of delivery**
 Alternate etiologies ruled out**
 >2-3 cm dilation**