Title: **Role of Platelet Rich Plasma in supporting the recovery of post-partum Levator Ani Muscle trauma**

Running title: **Platelet rich plasma in levator ani muscle trauma**

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STUDY PROTOCOL

Participant Flow

We obtained 245 primigravid women. As many as 85 subjects underwent caesarean section because of clinical indications, 39 subjects were failed to follow the study until the end and 5 subjects were found to have avulsion after 40 days post-partum. Overall, there were 58 subjects who successfully followed the examination until the end of the study.

Study Procedure

a. All patients who come to Polyclinic in Public Health Center (Puskesmas) will be taken a history and physical examination to determine whether the patient meets the criteria or not,
b. Patients who met the criteria were provided with information about this study. Patients who are willing will be asked to fill out an informed consent. If the patient refuses to participate in this study, the reasons for refusal must be written,
c. Randomization was performed and participant were divided into 2 groups (intervention group and control group). Participant will not know the results of randomization. Participant may know the results of randomization at the end of the study,
d. Initial data collection on study form and approval to participate will be taken. Participants are required to write down their full name, complete address, phone number, and family phone number. This is an attempt to increase the participation rate.
e. Participant will be examined by ultrasound to assess pelvic floor biometry, perineometry to assess pelvic floor muscle strength,
f. At delivery day, the participant in intervention group will be taken whole blood for preparation of 32 mL of PRP. After the PRP is ready, it will be injected directly into the levator ani muscle during post-partum perineorrhaphy,
g. Participant in control group will still have whole blood taken for examination (complete blood count) but no PRP preparation will be carried out. During perrineorrharphy will be injected lidocaine 1%. In this way, it is hoped that the participant will now know that she is in the intervention or control group,
h. At 40 days and 3 months post- partum, the levator hiatal area was assessed using ultrasound examination and levator ani muscle strength was assessed by perineometry. The ultrasound operator does not know the patient group.

Standard Operational Procedure 1 - Perineometry Examination

1. Patient was asked to take off her pant and underwear, then wear what has been provided,
2. The perineometer tool used is Peritron TM, this tool has a vaginal sensor with T valve inflation, connecting tube, collar, and display unit,
3. Plug in the connecting tube to the display unit,
4. Activate Peritron TM by pressing the power button. The screen should shows at zero,
5. Select the appropriate mode using 3 WTS (3 way toggle switch). In DISPLAY mode, select NO to select numeric mode. Next in DEVICE mode, select PERI for measurement of pelvic floor muscle strength,
6. When using the vaginal sensor, grab the sensor at the tail of the connector on the connecting tube,

7. Sensor insertion was performed with the subject in the supine position and place pillow (1-2 pieces) on patient's head, knees formed 90 degrees, 45 degrees between the thighs and the examination bed, knees and feet separated by 30 cm,
8. The operator wears gloves. Insert the sensor (wrapped with a condom) until it leaves 1 cm in front of the vagina,
9. Then do inflation using a syringe on the T valve, inject air up to 100 cm. Pull back the plunger, turn the valve to position T and release the syringe,
10. Press and release the button on the display unit until it shows a zero,
11. Ask the subject to 'pinch' the sensor as hard and as long as possible,
12. Data will be stored in PEAK, AVERAGE, DURATION, GRADIENT, and AREA UNDER CURVE modes,
13. DURATION will be read in seconds, starting from pressure above 5 cmH_2O to below 5 cmH_2O,
14. AVERAGE is AREA UNDER CURVE/DURATION,
15. PEAK is the maximum value in cmH_2O unit,
16. GRADIENT is in cmH_2O. GRADIENT is the maximum value divided by the time it takes to reach the maximum value (to measure onset),
17. AREA UNDER CURVE is the length of contraction multiplied by the average value of muscle strength (AVERAGE),
18. Remove the sensor,
19. Wiping the subject's genital area and allowing the subject to change clothes.

Standard Operational Procedure 2 – Pelvic Floor Ultrasonography Examination

1. After perineometry examination, the patient will underwent 3D ultrasonography examination to measure the integrity of the levator ani muscle and levator hiatal area,
2. The transducer is wrapped with a condom before placing it on the perineum,
3. Imaging is performed when the patient is in a dorsal lithotomy position (the hips are flexed and slightly abducted), after the bladder has been emptied,
4. Display a 2D image, position it so that the symphysis pubis, bladder, vagina, anorectal to levator ani are included in the volume which will be displayed in 4D,
5. Measure the hiatal area by pressing the point area on the screen and measure the hiatal area by tracing the edge of the hiatal,
6. Subjects were asked to do valsalva maneuver 2 times, measuring the left and right LUG (levator urethral gap) distance on 3 central Tomographic Ultrasound Imaging (TUI) images. If the distance is > 25 mm, then there is a levator ani avulsion,
7. Wipe the patient's genital area with a tissue and allow the patient to change clothes,
8. Ultrasound results will be validated by an expert (which is different from the USG operator).