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Management of Gestational Trophoblastic Diseases

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Management of gestational trophoblastic diseases

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1. Introduction

Gestational trophoblastic diseases (GTD) are a rare group of disorders that sometimes require a multi-disciplinary approach, principally the medical oncologist, for the best outcome. Though some are malignant, the outcome remains excellent if the correct treatment is given at the correct time. This guideline aims to achieve uniformity in how these patients receive care in the gynaecological clinical setting, with evidence-based recommendations and expert opinion.

2. Diagnosis, definitions and classifications

Gestational trophoblastic diseases (GTD) are a heterogeneous group of pregnancy-related diseases that include premalignant diseases (complete hydatidiform mole, partial hydatidiform mole) as well as malignant counterparts (invasive mole, gestational choriocarcinoma, placental site trophoblastic tumour, epithelioid trophoblast tumour). The malignant potential of atypical placental site nodules (PSNs) remains unclear.

2.1. **Molar pregnancy**

This represents the premalignant members of GTD, i.e., complete hydatidiform mole (CHM) and partial hydatidiform mole (PHM). These are diagnosed histologically. It is well-recognized that molar pregnancies are formed due to an imbalance between the maternal and paternal haploid chromosomes.

2.2 **Gestational trophoblastic neoplasia (GTN)**

It is the presence of any evidence of persistence of GTD after primary treatment, most commonly defined as a persistent elevation of human chorionic gonadotrophin (hCG). The diagnosis of GTN doesn't always require histological confirmation, and it represents the malignant subgroup of the spectrum of disease. High persistent hCG after evacuating hydatidiform mole is known as post-molar GTN. Invariably, all the subtypes would have high persistent hCG. The subtypes of GTN are as follows:

2.2.1 **Postmolar GTN**

It is diagnosed by the persistence of hCG following primary treatment of CHM and PHM. Usually, it is a biochemical diagnosis (See below). Postmolar GTN occurs in around 15-20% after CHM and in 1-5% after PHM[1].

2.2.2 **Invasive mole**

This is a histological diagnosis with invasion into uterine muscle and blood vessels. It occurs only following molar pregnancies. Even though it is considered a locally invasive disease, 15% of Invasive moles can metastasise to the lungs and vagina.

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2.2.3 **Choriocarcinoma**

This is a histological diagnosis which can occur following any type of pregnancy (Normal/Ectopic/ Molar). It has a high incidence of metastasis.

2.2.4 **Placental site trophoblastic tumour (PSTT)/ Epithelioid trophoblastic tumour (ETT)**

This is a histological diagnosis and can occur following any type of pregnancy (Normal/Ectopic/ Molar). Usually, there is a long interval from the last known pregnancy, and they often show varied production of hCG. Up to 50% of patients can have distant metastases at the time of diagnosis (commonly to the lungs). Unlike other malignant counterparts, lymphatic spread is also seen in these subtypes.

3. Investigations

3.1 **At the Initial presentation of a possible molar pregnancy**

3.1.1 **Ultrasound scan**

This remains the primary method of preoperative diagnosis. Due to the widespread availability of ultrasound scanning, molar pregnancies rarely go unnoticed beyond the 1st trimester. The classical ultrasound features, such as a snowstorm or honeycomb appearance, may not be seen in the early ultrasound scans. The cystic appearance of the placenta without an identifiable gestational sac may indicate early CHM, while an empty gestational sac or missed miscarriage with cystic/enlarged placenta can suggest PHM.

3.1.2 **Serum hCG level**

Serum hCG is elevated in all types of GTD. It is an excellent biomarker of disease progression, response, and subsequent post-treatment surveillance. Therefore, all patients should have a baseline serum hCG level before surgical evacuation. If a patient has to undergo an emergency surgical evacuation before the hCG level can be done, a blood sample should be drawn before the surgery for hCG assay. An hCG assay that detects all hCG forms (beta-hCG, core hCG, C-terminal hCG, nicked-free beta, beta core) is preferred. However, the availability of such comprehensive assays is limited in Sri Lanka.

3.1.3 **Chest X-ray**

The lungs are the most common site of metastasis in GTN. Therefore, all patients should have a chest X-ray before uterine evacuation.

3.2 **In choriocarcinoma/ PSTT/ ETT or suspected metastasis**

These conditions are known to be associated with a high incidence of distant metastasis. Therefore, further imaging is required to stage the disease before planning further treatment.

a. CT head, thorax, abdomen and pelvis in all patients
b. MRI head if choriocarcinoma or pulmonary metastases are present or in the presence of neurological symptoms.

4. Management

4.1 **Primary management of molar pregnancy**

4.1.1 **Surgical evacuation**

Suction curettage is the treatment of choice. This should be done under ultrasound guidance where facilities are available[2]. Priming of the cervix with prostaglandins immediately before surgical evacuation can be performed safely[3].

All specimens should be sent for histological assessment. In addition, retained products of conception (RPOC) of all miscarriages where no fetal parts are identified at any stage of the pregnancy should also undergo histological evaluation. All Rh-negative patients undergoing evacuation due to suspected molar pregnancies should receive Anti D prophylaxis.

4.1.2. **Place of hysterectomy**

For women of reproductive age with CHM/PHM, a hysterectomy is not the first line of treatment. Women who are at least 40 years old and do not intend to become pregnant in the future, with probable molar pregnancy based on ultrasound characteristics and increased hCG, may be offered a total hysterectomy as a first option rather than uterine evacuation[4].

However, before suggesting a hysterectomy as the first line of treatment, one should take into account the excellent results following chemotherapy in cases where GTN occurs. Women should always be given uterine evacuation and follow-up as their first option in the management of molar pregnancy.

4.1.3. **Repeat surgical evacuation**

Repeat evacuation is not encouraged, especially in situations where hCG is > 5000 and/or high-risk disease (WHO > 6) or non-CHM/PHM histology[5]. Patients with the above risk factors should have an early referral to a medical oncologist since it is more in favour of GTN. Repeat evacuation should be considered only in situations with life-threatening bleeding in the background of significant retained products.

4.1.4 **Surveillance for postmolar GTN**

All patients should undergo weekly serum hCG measurements until it returns to normal levels. Subsequently,

- In cases of CHM where hCG normalises within 8 weeks of evacuation, monthly serum hCG assessments should be performed for 6 months from uterine evacuation.
- In cases of CHM where hCG normalises after 8 weeks of evacuation, monthly serum hCG assessments should be performed for 6 more months from the date of hCG normalisation. These women have a higher risk of having postmolar GTN.
- In cases of PHM, serum hCG should be checked in 1 month. If negative, surveillance can be stopped.

4.1.5. **Contraception during follow-up**

It is very important that women should not get pregnant while on surveillance following a molar pregnancy. While traditionally, only barrier methods were recommended, hormonal contraception such as combined oral contraceptive pills and progesterone-only contraceptives are safe following surgical evacuation[6,7,8]. The use of intrauterine devices should be avoided.

4.2 **Management of GTN**

4.2.1 **Postmolar GTN**

a. Diagnosis of postmolar GTN

This is often a biochemical diagnosis. The FIGO criteria for the diagnosis of postmolar GTN are as follows.

FIGO criteria for diagnosis of postmolar gestational trophoblastic neoplasia[9]

When the plateau of hCG lasts for four measurements over a period of 3 weeks or longer; days 1, 7, 14, 21.

When there is a rise in hCG for three consecutive weekly measurements over at least a period of 2 weeks or more; days 1, 7, 14.

If there is a histologic diagnosis of choriocarcinoma.

b. Treatment of postmolar GTN

If any of the FIGO diagnostic criteria for postmolar GTN are present, these patients should be referred to a medical oncologist for chemotherapy. Chemotherapy for GTN should only be provided by a specialist medical oncologist.

Once GTN is diagnosed, patients are further triaged into risk groups. According to the FIGO 2000 scoring system, a score of 6 and below is classified as Low risk and a score above 6 is considered high risk[9]. (Annex 1) low-risk patients are treated with single-agent chemotherapy (methotrexate or actinomycin D), while high-risk patients are treated with more complex multi-agent chemotherapy.

4.2.2 **Invasive mole**

This is a histological diagnosis. If diagnosed from a post-hysterectomy specimen on histology, the patient must be referred to the oncologist for chemotherapy.

4.2.3 **Choriocarcinoma**

This is a histological diagnosis. These patients need urgent referral to the oncologist for chemotherapy. They would also require further imaging to stage the disease.

4.2.4 **PSTT/ETT**

This is usually not responsive to chemotherapy. Surgical resection is the primary modality of treatment. However, due to the high incidence of metastasis, a staging CT scan should be performed prior to surgical planning. Hysterectomy and pelvic lymphadenectomy

would be the standard treatment. Excision of the metastatic deposits should be carried out if this can be achieved with acceptable risks. All patients need a referral to the oncologist.

All patients with GTN should undergo monthly serial serum hCG surveillance for 12 months after completing chemotherapy and should be strictly advised not to conceive during the surveillance period.

5. Special considerations

5.1 **Medical management of ectopic pregnancy and management of pregnancy of unknown location (PUL)**

The above should not be mixed up with GTN management. In all 3 instances, methotrexate is used. However, methotrexate used in postmolar GTN is complex and extended and should be done by a medical oncologist. It should be worth noting that GTN with non-molar index pregnancy (miscarriage, ectopic, normal pregnancy) can present as PUL. We advise being mindful of this fact when managing PUL.

5.2 **GTN patients with features of severe pre-eclampsia**

GTN patients may complain of severe headaches, blurred vision, and vomiting. These patients must be checked for hypertension, exaggerated reflexes/clonus and proteinuria. They may need ICU care, stabilising blood pressure, intravenous magnesium sulphate and fluid management as per pre-eclampsia protocol. Permanent treatment would be an expedited suction evacuation or hysterectomy after initial stabilisation.

5.3 **GTN patients with severe vaginal bleeding**

To stop bleeding, either urgent suction evacuation or hysterectomy +/- internal iliac artery ligation may be required.

5.4 **GTN patients on chemotherapy presenting with hypovolemic shock due to uterine rupture**

Urgent exploratory laparotomy, evacuation of products, repair of the uterus/hysterectomy, and internal iliac artery ligation may be required to save the life of the woman.

5.5 **Prophylactic chemotherapy at the time of uterine evacuation**

Administration of methotrexate or dactinomycin at the time of or after evacuation has been shown to reduce the incidence of postmolar GTN by 3 - 8%. However, this should only be considered in high-risk patients such as women >40 years, hCG >100,000 mIU/ml, with excessive uterine enlargement or theca lutein cyst > 6cm. Long-term data on toxicity and drug resistance are still lacking[11,12]. Therefore, this decision should only be undertaken after a multi-disciplinary discussion and case-by-case consideration.

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Annexe: FIGO Scoring system

FIGO score	0	1	2	4
Age	<40	> 40	-	-
Antecedent pregnancy	Mole	Abortion	Term	
Interval from index pregnancy, month	<4	4-6	7-12	>12
Pretreatment hCG mIU/ml	$<10^3$	$>10^3$ - 10^4	$>10^4$ - 10^5	$>10^5$
Largest tumor size including uterus[a], cm	-	3-4	≥5	-
Site of metastases including uterus	Lung	Spleen, kidney	Gastrointestinal tract	Brain, liver
Number of metastases identified	-	1-4	5-8	>8
Previous falied chemotherapy	-	-	Single drug	Two or more drugs

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Cervical Cerclage

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Sri Lanka College of Obstetricians and Gynaecologists

Cervical cerclage

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1. Introduction

Preterm delivery and prematurity are the leading causes of perinatal morbidity, mortality and long-term adverse outcomes among the survivors[1]. Cervical incompetency is one of the major causes of second-trimester pregnancy loss, preterm delivery and preterm prelabour rupture of membranes (PPROM). A short cervical length is a significant risk factor or predictor of cervical incompetency[2].

Cervical insufficiency is an imprecise clinical diagnosis frequently applied to women with a history where it is assumed that the cervix is 'weak' and unable to remain closed during pregnancy[3]. Recent evidence suggests that, rather than being a dichotomous variable, cervical integrity is likely to be a continuum influenced by factors related not solely to the intrinsic structure of the cervix but also to processes driving premature effacement and dilatation[3].

Cervical cerclage is one of the standard prevention methods for second-trimester loss and preterm delivery. Cervical cerclage may provide a degree of structural support to a 'weak' cervix. However, it's role in maintaining the cervical length and the endocervical mucus plug as a mechanical barrier to ascending infection may be more important. Cervical cerclage was first demonstrated in 1955 by Shirodkar by placing a stitch around the cervix and enclosing it. Later, modifications were made to this stitch technique, and different types of cervical cerclage placement are now in practice[4].

2. Keywords and terminology

- ***Second-trimester pregnancy loss*** – Pregnancy loss/ miscarriage that occurs after 12 completed weeks to 24 weeks of gestation (up to the gestation of fetal viability)[5].
- ***Spontaneous preterm delivery*** – Spontaneous delivery of the fetus between 24 weeks and 36 weeks and 6 days of gestation[6].
- ***History indicated cervical cerclage*** – Application of cervical cerclage in asymptomatic women with a previous history that increases the risk of preterm birth[7].
- ***Ultrasound indicated cervical cerclage*** – Application of cervical cerclage in a woman with short cervical length on ultrasound scan[7].
- ***Emergency or rescue cerclage*** – Application of cervical cerclage in a woman who is diagnosed to have premature dilatation of the cervix and exposed fetal membranes when she is not in labour[7].

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3. When is cervical cerclage indicated?

- ***History indicated cervical cerclage*** – Women with a singleton pregnancy and three or more previous second-trimester losses or preterm births[5,8].
- ***Ultrasound indicated cervical cerclage*** – Women with a singleton pregnancy who have risk factors for preterm birth and a cervical length <25mm[5,9].

Ultrasound evidence of funneling alone without shortening of the cervix is not an indication for ultrasound-indicated cervical cerclage. The obstetrician should discuss it with the woman, and an individual decision should be made[10].

Cervical cerclage is not indicated in women with a history of two or fewer previous preterm births or second-trimester loss[5,7].

Cervical cerclage is not indicated in women with no risk factors for preterm birth or second-trimester loss and an incidental finding of cervical length <25mm[5,11,12].

Pregnancy following IVF and uterine anomalies alone are not indications for cervical cerclage in the absence of other risk factors[10].

4. Risk factors for preterm birth or second-trimester loss

- Those with a previous preterm birth or second-trimester loss (16-34 weeks gestation)
- Previous preterm prelabour rupture of membranes (PPROM) at less than 34 weeks gestation
- Previous use of cervical cerclage
- History of trachelectomy
- Known uterine variant / structural abnormality
- Intrauterine adhesion

5. Screening for cervical insufficiency

Whom to screen?

- Previous second-trimester loss
- Previous spontaneous preterm delivery at <34 weeks gestation and no other cause
- Previous >1 LLETZ procedure
- Previous cone biopsy of cervix
- Previous cervical surgeries such as trachelectomy
- Known uterine anomaly

How and when to screen?

- Serial transvaginal ultrasound scans are recommended every two weeks from 16 weeks to 24 completed weeks of gestation[13,14].

There is insufficient evidence to recommend universal screening for cervical insufficiency[13].

6. What are the contraindications for cervical cerclage?

The following are considered contraindications for insertion of cervical cerclage[5,15].

- Active preterm labour
- Evidence of chorioamnionitis
- Continuing vaginal bleeding
- PPROM
- Evidence of fetal compromise
- Lethal fetal defect
- Fetal death

7. Types of cervical cerclage

Trans-vaginal cerclage

- McDonald technique – A transvaginal purse-string suture is placed at the vaginal part of the cervix without bladder mobilisation[5].
- Shirodkar technique – A transvaginal purse-string suture is placed following bladder mobilisation to allow insertion above the level of the cardinal ligaments[5].

Trans-abdominal cerclage

- A suture is placed at the cervico-isthmic junction and performed via a laparotomy or laparoscopy[5].

Selecting the type of cervical cerclage depends on the indication, skill of the operator and individual circumstances.

8. Which cervical cerclage method is better?

Comparing Shirodkar and McDonald cerclage, the former is theoretically effective as it is placed higher near the cervico-isthmic junction. But it has practical difficulties such as needing bladder dissection, requiring an experienced surgeon, and difficulties in removal.

A randomised controlled trial showed no significant difference in the preterm delivery or fetal loss rates between upper and lower vaginal cerclage but fewer preterm deliveries and fetal loss rates in abdominal cerclage compared to lower vaginal cerclage[16].

As good clinical practice, we recommend a transvaginal cerclage placed as high as possible without dissection of the bladder, although there is inadequate evidence to recommend it. Further research is required in this area.

Trans-abdominal cerclage is recommended for women with previously failed vaginal cerclage and in women with a history of previous cervical surgery such as trachelectomy or a severely distorted cervix[16]. Trans-abdominal cerclage is not recommended as a first-line option unless it is indicated.

In the case of a previously failed McDonald cerclage, a detailed assessment should be carried out by an experienced clinician following which the application of either Shirodkar or an abdominal cerclage should be done by an experienced and skilled surgeon[17].

A trans-abdominal cerclage can be done via laparoscopy or laparotomy. Available evidence shows no significant difference in the efficacy. However, laparoscopic cerclage has less surgical morbidity, although it requires a skilled operator.

9. What is the preferred suture material?

A non absorbable suture material is recommended for cervical cerclage. The choice of suture material should be at the discretion of the surgeon.

Current evidence shows no significant difference in preterm birth rates between single and double sutures. Therefore, double sutures are not recommended.

10. Pre-operative preparations

All pregnant women awaiting cervical cerclage should have a first-trimester ultrasound scan or an anomaly scan to exclude gross fetal anomalies depending on the gestation.

Informed written consent should be obtained after explaining the procedure and possible adverse effects or complications to the patient. Cervical cerclage is associated with a small risk of intraoperative bladder damage, cervical trauma, membrane rupture and bleeding[5].

Screening for infection using WBC count and CRP should be carried out before emergency cerclage if there is a clinical suspicion of infection. A urine full report (UFR) and a high vaginal swab for culture can be considered before a cervical cerclage to screen for genito-urinary infection. There is insufficient data to recommend amniocentesis to screen for chorio-amnionitis in women awaiting emergency cerclage.

There is no evidence to support the use of routine perioperative tocolysis in women undergoing cervical cerclage[9].

Preoperative antibiotic prophylaxis can be decided according to local protocol, as there is no evidence to recommend routine antibiotic prophylaxis[9].

11. Post-operative care

There is no evidence to recommend bed rest routinely. Bed rest following cervical cerclage should be considered on an individual basis. It is also necessary to consider the adverse effects of prolonged immobilisation[18].

Abstinence from sexual intercourse following cerclage insertion should not be routinely recommended[15].

There is insufficient evidence to recommend progestogen therapy following cervical cerclage routinely. A systemic review and meta-analysis of 5 studies comparing cerclage alone and cerclage with adjuvant progesterone treatment concluded that intramuscular 17α-hydroxyprogesterone caproate (17-OHPC) in combination with prophylactic cerclage in women with prior preterm birth had no synergistic effect in reducing spontaneous recurrent preterm birth or improving perinatal outcomes[19].

The neonatal team should be informed after a successful emergency rescue cervical cerclage, and the availability of neonatal care facilities should be confirmed. If neonatal care facilities are unavailable, consider in-utero transfer[20].

There is insufficient data to recommend tocolysis therapy following cervical cerclage[21]. However, tocolytics can be used 48 hours following cervical cerclage.

12. When should a cervical cerclage be removed?

No trials are comparing the timing of cerclage removal. Cerclage should be removed before the onset of labour to prevent cervical trauma. If a woman does not go into spontaneous preterm labour, it is recommended to remove the cervical cerclage between 36 to 37 weeks of gestation to balance the risk of preterm delivery and fetal maturity[5].

Cervical cerclage should be removed as early as possible in women presenting with established preterm labour because dilatation of the cervix while the cervical cerclage is in place, can result in cervical trauma.

Removal of cervical cerclage can be delayed up to 48 hours in women presenting with PPROM, as it can delay the latency period, allowing time for the action of maternal corticosteroids. A retrospective study showed that delaying the removal of cervical cerclage for 24 hours following PPROM resulted in an increased time period from PPROM to delivery by 70.4 hours. But there is also a small increase in the rate of chorioamnionitis in women who had delayed removal (60% vs 45%)[22].

Women with high vaginal cerclage (Shirodkar) need anaesthesia for cerclage removal. Bladder dissection should be performed to reach the suture.

Women who have had an abdominal cerclage should undergo a prelabour elective caesarean section. The cerclage can be left in situ and does not necessarily need to be removed.

13. Cervical cerclage in multiple pregnancy

A multiple pregnancy is not an indication of cervical cerclage. A meta-analysis of five trials assessed the use of cerclage in multiple pregnancies; 122 women had twin pregnancies, and 6 had triplet pregnancies. Studies included assessed history-indicated cerclage, ultrasound-indicated cerclage and physical exam-indicated cerclage. No statistical difference was found between the cerclage and non-cerclage groups for perinatal death, significant neonatal morbidity and preterm birth less than 34 weeks[23].

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