CASE REPORT

Intrathecal baclofen pump – a viable therapeutic option in pregnancy

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Summary: Baclofen, a gamma-aminobutyric acid analogue, is used as a muscle relaxant and antispasmodic to relieve symptoms in patients with intractable spasticity arising from cerebral or spinal aetiology such as in traumatic brain injury or multiple sclerosis. As it is often used in women of reproductive age, it is imperative to know the safety and associated maternal and fetal risks. The Food and Drug Administration has assigned the drug to Pregnancy Category C because of the lack of controlled data in humans. Animal studies have revealed an increased incidence of omphalocele if used in doses several times the recommended human dose. Baclofen should only be given during pregnancy when the benefits outweigh the risks. Baclofen is considered compatible with breast feeding by the American Academy of Pediatrics.

Keywords: high-risk pregnancy, maternal–fetal medicine

INTRODUCTION

The administration of baclofen is either orally in divided doses or via an intrathecal baclofen (ITB) pump.[1,2] Oral baclofen therapy leads to high plasma levels (0.08–0.4 μg/mL) and has been associated with neonatal withdrawal manifested as convulsions.[3] The ITB pump is Food and Drug Administration (FDA) approved for severe spasticity that is refractory to oral therapy. The dose used in ITB therapy is up to 100 times lower than that for oral therapy.[4] As this dose is administered directly into the intrathecal space, the plasma levels are generally below detectable levels but have a therapeutic effect.

CASE

We report a case of a 34-year-old woman G2P0010 with spastic dyskinetic cerebral palsy secondary to a preterm delivery at 28 weeks. She also had seizure disorder, well-controlled Graves' disease and congenital deafness with bilateral cochlear implants. She was wheelchair bound with severe contractures. Her medications included levetiracetam, topiramate, clonazepam, propylthiouracil, prenatal vitamins and folic acid. One year prior to her pregnancy she had an ITB pump implanted because of severe spasticity refractory to oral therapy and became controlled with the ITB pump.

The patient conceived spontaneously and, after appropriate counselling, she elected to continue her pregnancy. She had several seizures during the course of her pregnancy for which she needed inpatient evaluation and admission with appropriate dose adjustments. The maternal–fetal medicine specialist and neurologist closely monitored her during her pregnancy. As her pregnancy progressed, she developed increasing spasticity necessitating baclofen dosage adjustment. Towards the end of her pregnancy she was receiving 640 μg/day via the pump. This was three times her prepregnancy dose but within the safe therapeutic range. Titration was carried out in accordance with clinical response and baclofen levels were not drawn.

The patient received genetic counselling for advanced maternal age, and detailed counselling regarding possible effects of the various medications she was taking, maternal neurological illness, thyroid disease and especially the seizures. The first trimester screen for chromosomal anomalies was normal. The second trimester anatomy scan was normal. Her pregnancy was monitored with serial growth assessments every 3–4 weeks and weekly antepartum testing with biophysical profiles. At 31 weeks gestational age, an abrupt increase in amniotic fluid volume was detected (amniotic fluid index 32 cm), as was an intra-abdominal umbilical vein varix. The work-up for sudden, acute polyhydramnios was negative. Antepartum testing was continued until 33 weeks when a scheduled delivery was planned for fetal indication, after steroid administration for fetal lung maturity, due to abnormal biophysical profile assessment. She underwent an uneventful low transverse cervical caesarean section under epidural anaesthesia. There was no difference in the technique of the epidural analgesia as the ITB pump catheter was not located near the L3–4 level. The pump reservoir was in the anterior abdominal wall, but away from the region of a usual Pfannenstiel incision. The caesarean delivery could be accomplished in the usual manner. We did not need to make any modifications in the technique as the location of the pump and its catheter did not interfere with our procedure.

An appropriate for gestational age morphologically normal, female infant with birth weight 2060 g and Apgar scores 6 and 7 was delivered. The infant had poor tone in the first few minutes of life. The subsequent neonatal neurological

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examination was normal. The infant remained in the neonatal intensive care unit for prematurity and was discharged home on day 12 in a stable condition. The patient had an uncomplicated postoperative period and was discharged home on postoperative day 3. The ITB dosing was not changed after delivery and was maintained at 640 μg/day. The patient had satisfactory control of her symptoms and was able to safely hold her child. She elected not to breast feed, although this was not contraindicated. She was re-admitted on postoperative day 6 due to uncontrolled seizures, and given intravenous levetiracetam to which she responded well. Eclampsia was ruled out because she was normotensive, with normal preeclamptic laboratory values and absence of proteinuria. The patient was subsequently discharged home three days later following appropriate dosage adjustments of levetiracetam.

COMMENT

Previous case reports on baclofen usage during pregnancy have shown no major problems, although follow-up was limited. In one case report there was adequate control of spasticity in the patient until 35 weeks gestation when a recurrence was noted. This was attributed to autonomic dysregulation. The infant was delivered by a primary caesarean section.[5] In another report, the newborn of a mother on oral baclofen presented on day 7 of life with generalized convulsions unresponsive to standard anticonvulsant therapies. However, the neonate responded to baclofen. The dosage was slowly tapered off and the neonate did not have any recurrent seizure activity.[3] Oral baclofen therapy leads to higher plasma levels in the mother and hence may be associated with neonatal withdrawal. Maternal intrathecal administration may be a safer option as it reduces fetal exposure levels and hence the side-effects. Thus, we suggest that the baclofen intrathecal pump should be considered a viable therapeutic option in pregnant patients.

In our case, the fetus was diagnosed with an intra-abdominal umbilical vein varix, which arose in the third trimester. It is unclear as to whether this could be attributed to one of the several medications the mother was on, even though none of them have been associated with such abnormalities. Previous reports about intra-abdominal umbilical vein varices have described an association with intrauterine fetal death, chromosomal abnormality and hydrops fetalis, and thus may serve as a warning sign of impending poor pregnancy outcomes.[6] Fetal demise occurs due to worsening fetal hydrops or thrombosis of the umbilical vein. In cases such as ours, which have no other associated findings, the prognosis is usually good. The presence of umbilical vein varices is clinically irrelevant in the neonate as there is spontaneous resolution of this abnormality after clamping of the cord and reversal of the fetal circulation.

There was the development of unexplained polyhydramnios in our case at about 31 weeks gestation. There was no obvious explanation for this development. One possibility was that it could be arising from impaired fetal swallowing due to the muscle relaxant effect of baclofen.

Our patient had adequate control of her spasticity and tolerated the ITB pump well during the course of her pregnancy. This was similar to the course described in previous reports in the literature. Moreover, the pump was located away from the area of the caesarean section incision and this was also not a concern for the anaesthesiologist during epidural placement. The location of the pump and its catheter was ascertained from the operative report of the pump insertion procedure. This can become an important factor to consider in patients with external catheters.[4] There is usually no need to move the actual location of the pump during the course of pregnancy because it usually moves lateral and hence closer to the spine as the pregnancy progresses.

We conclude that ITB pump therapy should be considered for use during pregnancy. The initiation of ITB pump therapy during pregnancy has been reported in the literature with successful outcomes. Pregnancy should not be a reason to withhold this treatment modality in appropriate patients. Consideration should be given to the anatomic location of the pump in women who desire future childbearing, as its location may cause a problem during operative deliveries. The risks and possible benefits should be fully explained to the patient and these should be considered prior to use. Antenatal communication with the patient and members of her care team regarding possible outcomes has been shown to be very important for ensuring effective management.[7] A multidisciplinary team approach is strongly recommended and should be tailored to the individual patient so as to form an appropriate treatment plan that can lead to a successful outcome.

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