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Clinical practice evaluation of atosiban in preterm labour management in six European countries

Sir,

Husslein *et al.* in their paper on the clinical evaluation of atosiban in preterm labour management provide no guidance for practice on the use of atosiban and lactation.[1]

A drug that delays premature labour without major cardiovascular adverse effects is welcome. Clinical trials and systematic reviews have showed similar effectiveness and reduced adverse effects of atosiban, an oxytocin inhibitor, in comparison with other commonly used tocolytics, both beta-agonists and calcium channel blockers. However, the effect on lactation has not been a routine part of the safety profiling of atosiban. Oxytocin plays an important part in the physiology of lactation, as it stimulates milk ejection through the 'let-down reflex'.

A short half-life and greater uterine specificity are possible explanations for ignoring potential adverse effects on breastfeeding. Despite these reassurances, animal studies have shown that atosiban does impair lactation in rats[2] and has a powerful effect in inhibiting milk ejection in dairy cows.[3] While atosiban has a short half-life of 12–18 minutes, its effect could extend into the early postpartum period with disruption to the first feed, as it is possible that the birth may occur during or shortly after atosiban infusion. Timing of the first feed significantly contributes to successful breastfeeding and directly impacts on the duration of breastfeeding. Atosiban is promoted as being specific to oxytocin receptors in the uterus, but how specific is it? Is it 100% specific to uterine receptors with no effect on breast-specific oxytocin receptors or has it some effect?

Lamont[4] states that there is a theoretical risk of impaired breastfeeding with atosiban but goes onto state that it is negligible. Yet, there is no quantitative evidence of 'no effect' in the clinical trial literature. Husslein *et al.* go to considerable lengths to classify adverse events of atosiban as mild, moderate and severe with a further subcategorisation of probable, possible, unlikely and unrelated to atosiban and yet a theoretical, biologically plausible adverse effect on lactation, which is evident in animal studies, is completely ignored in phase IV clinical trial.

We acknowledge that delaying delivery by 48 hours has a significant impact on neonatal outcomes. However, information about the effects, if any, of atosiban on breastfeeding is absent. No evidence of an effect, when it has not been looked for, is not the same as the robust evidence of no effect. This information is essential to provide evidenced based breastfeeding support to the woman with a premature baby who was administered atosiban. If it adversely affects the chances of successful breastfeeding, then additional and timely support will be required. ■

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