

## RECOMENDACIÓN T.10

### BÚSQUEDA Y SÍNTESIS DE EVIDENCIA DE EFECTOS DESEABLES E INDESEABLES

#### Guía de Práctica Clínica Trastorno Bipolar en personas de 15 años y más - 2018

##### A. PREGUNTA CLÍNICA

En personas con trastorno bipolar en fase de mantención con embarazo en curso (segundo y tercer trimestre) ¿Se debe usar litio como monoterapia en comparación a usar antipsicóticos atípicos como monoterapia?

##### Análisis y definición de los componentes de la pregunta en formato PICO

**Población:** Personas con trastorno bipolar en fase de mantención con embarazo en curso (segundo y tercer trimestre).

**Intervención:** Litio como monoterapia.

**Comparación:** Antipsicóticos atípicos como monoterapia.

**Desenlace (outcome):** Desarrollo neurológico, malformaciones, problemas en el parto.

##### B. BÚSQUEDA DE EVIDENCIA

Se realizó una búsqueda general de revisiones sistemáticas asociadas al tema de “Bipolar affective disorder”. Las bases de datos utilizadas fueron: Cochrane database of systematic reviews (CDSR); Database of Abstracts of Reviews of Effectiveness (DARE); HTA Database; PubMed; LILACS; CINAHL; PsycINFO; EMBASE; EPPI-Centre Evidence Library; 3ie Systematic Reviews and Policy Briefs Campbell Library; Clinical Evidence; SUPPORT Summaries; WHO institutional Repository for information Sharing; NICE public health guidelines and systematic reviews; ACP Journal Club; Evidencias en Pediatría; y The JBI Database of Systematic Reviews and implementation Reports. No se aplicaron restricciones en base al idioma o estado de publicación. Dos revisores de manera independiente realizaron la selección de los títulos y los resúmenes, la evaluación del texto completo y la extracción de datos. Un investigador experimentado resolvió cualquier discrepancia entre los distintos revisores. En caso de considerarse necesario, se integraron estudios primarios.

Seleccionadas las revisiones sistemáticas o estudios primarios asociadas a la temática, se clasificaron en función de las potenciales preguntas a las que daban respuesta. Al momento de definir la pregunta la evidencia ya se encontraba previamente clasificada según intervenciones comparadas. Los resultados se encuentran alojados en la plataforma Living Overview of the Evidence (L-OVE), sistema que permite la actualización periódica de la evidencia.

## C. SÍNTESIS DE EVIDENCIA

### Resumen de la evidencia identificada

Se identificaron 15 revisiones sistemáticas que incluyen 314 estudios primarios, de los cuales ninguno corresponde a ensayos aleatorizados. Para más detalle ver “*Matriz de evidencia*”<sup>1</sup>, en el siguiente enlace: [Efecto adverso del litio y antipsicóticos atípicos en el embarazo](#).

Tabla 1: Resumen de la evidencia seleccionada

Revisión Sistemática	15 [1-15]
Estudios primarios	311 [16-326]

\*Si bien uno de los artículos no corresponde a una revisión sistemática, sino a metanálisis de cohortes específicas (sin revisión) se decidió conservar ya que entrega información relevante. Además, no se encontró el texto completo de dos revisiones sistemáticas más amplias, pero es poco probable que contengan estudios relevantes no encontrados por el resto de las revisiones sistemáticas.

### Estimador del efecto

Se realizó un análisis de la matriz de evidencia, observando que no hay estudios que comparen litio contra antipsicóticos en embarazo, por lo cual se decidió analizar una comparación indirecta. Además, ninguna de las revisiones sistemáticas pudo realizar metanálisis por lo cual se decidió presentar las conclusiones de manera narrativa.

### Metanálisis

No aplica.

<sup>1</sup> **Matriz de Evidencia**, tabla dinámica que grafica el conjunto de evidencia existente para una pregunta (en este caso, la pregunta del presente informe). Las filas representan las revisiones sistemáticas y las columnas los estudios primarios que estas revisiones han identificado. Los recuadros en verde corresponden a los estudios incluidos en cada revisión. La matriz se actualiza periódicamente, incorporando nuevas revisiones sistemáticas pertinentes y los respectivos estudios primarios.

Tabla de Resumen de Resultados (Summary of Findings)

LITIO COMPARADO CON ANTIPSICÓTICOS PARA EMBARAZO.			
Pacientes	Personas con trastorno bipolar en fase de mantención con embarazo en curso (segundo y tercer trimestre).		
Intervención	Litio como monoterapia.		
Comparación	Antipsicóticos atípicos como monoterapia.		
Desenlaces	Efecto	Certeza de la evidencia (GRADE)	Mensajes clave en términos sencillos
Desarrollo neurológico	Tres cohortes en una revisión [14] no encontraron diferencias en desarrollo neurológico al utilizar litio comparado con no usarlo. Dos cohortes en una revisión [14] no encontraron diferencias en desarrollo neurológico al utilizar antipsicóticos atípicos comparado con no usarlo y 7 cohortes en una revisión [14] encontraron diferencias en diversos ámbitos como actividad motora, abstinencia, cognición, socio-emocional, conductual.	⊕○○○ <sup>1,2,3</sup> Muy baja	No está claro si litio comparado con antipsicóticos atípicos tiene diferencia en desarrollo neurológico en mujeres embarazadas.
Malformaciones	Un estudio de casos y controles [55] presenta un OR 2,62 (IC 95% 0,74 a 9,20) para malformaciones por uso de litio. A su vez una revisión sistemática reporta RR 1,0 (IC 95% 0,7 a 1,4) para olanzapina, RR 1,0 (IC 95% 0,6 a 1,7) para quetiapina, RR 1,5 (0,9 a 2,2) para risperidona y 1,4 (IC 95% 0,5 a 3,1) para aripiprazol.	⊕○○○ <sup>1,2,3</sup> Muy baja	No está claro si litio comparado con antipsicóticos atípicos tiene diferencia en malformaciones en mujeres embarazadas.
Problemas en el parto	Una cohorte de una revisión sistemática reportó una incidencia de 37% de partos prematuros en mujeres utilizando litio. Una revisión sistemática [12] presenta un aumento de algunas complicaciones como posturas anormales, tono reducido y epilepsias. Sin embargo, estos corresponden a reportes de casos con el uso de clozapina. Otra revisión sistemática [6] reporta casos de taquicardia neonatal, insuficiencia respiratoria. Además, en un estudio de esta revisión [6] se reporta un aumento de parto prematuro con OR 2,57 (IC 95% 1,06 a 6,27) y retraso del crecimiento con OR 2,97 (IC 95% 1,23 a 7,16) utilizando aripiprazol.	⊕○○○ <sup>1,2,3</sup> Muy baja	No está claro si litio comparado con antipsicóticos atípicos tiene diferencia en problemas en el parto en mujeres embarazadas.
Complicaciones metabólicas	No se identificaron revisiones sistemáticas que reporten acerca de complicaciones metabólicas del embarazo como diabetes gestacional o hipoglicemia del recién nacido.	--	--

IC 95%: Intervalo de confianza del 95% // RR: Riesgo relativo //

GRADE: Grados de evidencia Grading of Recommendations Assessment, Development and Evaluation.

<sup>1</sup> Diseño observacional.

<sup>2</sup> Se disminuyó un nivel de certeza de evidencia ya que la mayoría de los estudios presenta pérdidas importantes de pacientes y corresponden a estudios retrospectivos.

<sup>3</sup> Se disminuyó un nivel de certeza de evidencia por inconsistencia ya que diferentes estudios presentan diferentes conclusiones.

<sup>4</sup> Se disminuyó un nivel de certeza de evidencia por imprecisión ya que, si bien no hubo intervalo de confianza en muchas conclusiones, debido a la baja tasa de eventos es muy probable que el intervalo fuera muy amplio.

<sup>5</sup> Se disminuyó dos niveles de certeza de evidencia por indirecto, ya que corresponde a una comparación indirecta sin metodología de network metanálisis, por lo cual las diferencias pueden explicarse por otras características en los estudios y no solamente por la intervención/comparación. Además, se decidió no disminuir certeza adicional pese a ser en otras enfermedades ya que el efecto adverso investigado principalmente es secundario uso en embarazo (Además, la gran mayoría de los estudios proviene de población bipolar).

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