RECOMENDACIÓN T1

BÚSQUEDA Y SÍNTESIS DE EVIDENCIA DE EFECTOS DESEABLES E INDESEABLES

Guía de Práctica Clínica Ataque cerebrovascular - 2018

A. PREGUNTA CLÍNICA

En personas con diagnóstico de ataque cerebrovascular (ACV) isquémico con confirmación radiológica con oclusión de gran vaso intracraneal, ¿Se debe realizar trombolisis intravenosa + trombectomía mecánica intraarterial en comparación a realizar trombolisis intravenosa?

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

Población: Personas con diagnóstico de ataque cerebrovascular (ACV) isquémico con confirmación radiológica con oclusión de gran vaso intracraneal

Intervención: Trombolisis intravenosa + trombectomía mecánica intraarterial.

Comparación: Trombolisis intravenosa.

Desenlace (outcome): Mortalidad, funcionalidad, hemorragia intracraneal sintomática.

B. BÚSQUEDA DE EVIDENCIA

Se realizó una búsqueda general de revisiones sistemáticas asociadas al tema de "Stroke". 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.[1]

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.

[1] Para revisar la metodología, las estrategias y los resultados de la búsqueda, favor revisar el informe "*Búsqueda sistemática de evidencia de los efectos deseables e indeseables*" en la sección de método de la Guía de Práctica Clínica respectiva.

C. Síntesis de evidencia

Resumen de la evidencia identificada

Se identificaron 34 revisiones sistemáticas que incluyeron 85 estudios primarios, de los cuales 13 corresponden a ensayos aleatorizados. Para más detalle ver "*Matriz de evidencia*"[2], en el siguiente enlace: Trombectomía mecánica para accidente cerebrovascular agudo.

Tabla 1: Resumen de la evidencia seleccionada

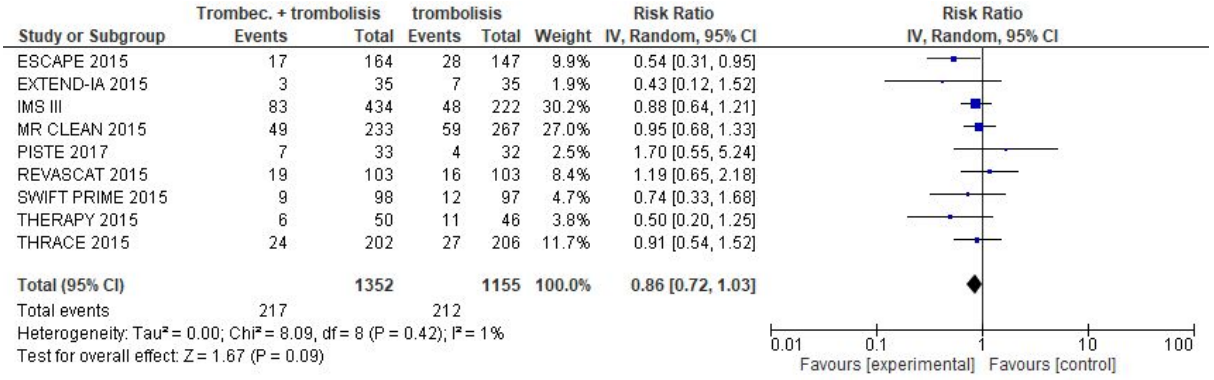
Revisión Sistemática	34 [1-34]
Estudios primarios	13 ensayos aleatorizados [35-47], 73 estudios observacionales [48-119]

Estimador del efecto

Se realizó un análisis de la matriz de evidencia, decidiendo excluir 2 ensayos [36, 37] debido a que no permitieron trombolisis intravenosa previo a trombectomía mecánica, un ensayo comparó dos técnicas de trombectomía [35] y otro que evalúa el rol de una tomografía para la trombectomía [42]. Se identificaron tres revisiones sistemáticas [7,10,22] que en conjunto incluyeron todos los ensayos aleatorizados relevantes [38-41, 43-47], por lo que se decidió reutilizar sus metanálisis para construir la tabla de resumen de resultados. Además, los estudios observacionales no entregaban información adicional relevante ni modificaban la certeza de la evidencia.

Metanálisis

Mortalidad

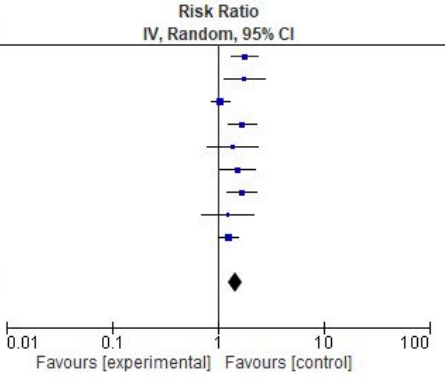


[2] **Matriz de Evidencia**, tabla dinámica que grafica el conjunto de evidencia existente para una pregunta (en este caso, la pregunta del presente informe). Las filas representan las revisiones sistemáticas y las columnas los estudios primarios que estas revisiones han identificado. Los recuadros en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

mRS 0 a 2

Study or Subgroup	Trombec. + trombolisis Events	Total	trombolisis Events	Total	Weight	Risk Ratio IV, Random, 95% CI
ESCAPE 2015	87	164	43	147	13.0%	1.81 [1.36, 2.42]
EXTEND-IA 2015	25	35	14	35	7.7%	1.79 [1.13, 2.82]
IMS III	177	415	86	214	17.2%	1.06 [0.87, 1.29]
MR CLEAN 2015	76	233	51	267	12.2%	1.71 [1.25, 2.32]
PISTE 2017	17	33	12	32	5.8%	1.37 [0.79, 2.40]
REVASCAT 2015	45	103	29	103	9.8%	1.55 [1.06, 2.27]
SWIFT PRIME 2015	59	98	33	93	11.9%	1.70 [1.23, 2.33]
THERAPY 2015	19	50	14	46	5.7%	1.25 [0.71, 2.19]
THRACE 2015	106	200	85	202	16.7%	1.26 [1.02, 1.55]
Total (95% CI)		**1331**		**1139**	**100.0%**	**1.45 [1.25, 1.69]**
Total events	611		367			

Heterogeneity: Tau² = 0.03; Chi² = 16.09, df = 8 (P = 0.04); I² = 50%
Test for overall effect: Z = 4.76 (P < 0.00001)



Hemorragia intracraneal sintomática

Study or Subgroup	Trombec. + trombolisis Events	Total	trombolisis Events	Total	Weight	Risk Ratio IV, Random, 95% CI
ESCAPE 2015	6	165	4	150	8.4%	1.36 [0.39, 4.74]
EXTEND-IA 2015	0	35	2	35	1.4%	0.20 [0.01, 4.02]
IMS III	27	434	13	222	31.6%	1.06 [0.56, 2.02]
MR CLEAN 2015	14	233	14	267	25.1%	1.15 [0.56, 2.35]
PISTE 2017	0	33	0	32		Not estimable
REVASCAT 2015	5	103	2	103	5.0%	2.50 [0.50, 12.59]
SWIFT PRIME 2015	0	98	3	97	1.5%	0.14 [0.01, 2.70]
THERAPY 2015	4	43	6	62	9.0%	0.96 [0.29, 3.20]
THRACE 2015	14	195	8	201	18.1%	1.80 [0.77, 4.20]
Total (95% CI)		**1339**		**1169**	**100.0%**	**1.19 [0.83, 1.71]**
Total events	70		52			

Heterogeneity: Tau² = 0.00; Chi² = 5.39, df = 7 (P = 0.61); I² = 0%
Test for overall effect: Z = 0.96 (P = 0.34)

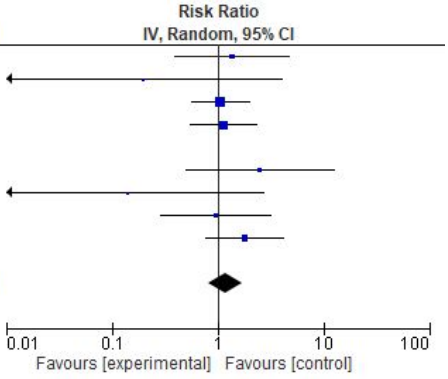


Tabla de Resumen de Resultados (Summary of Findings)

TROMBOLISIS INTRAVENOSA + TROMBECTOMÍA MECÁNICA INTRAARTERIAL VERSUS TROMBOLISIS INTRAVENOSA PARA ATAQUE CEREBROVASCULAR ISQUÉMICO.						
Población	Personas con diagnóstico de ataque cerebrovascular isquémico con confirmación radiológica con oclusión de gran vaso intracraneal.					
Intervención	Trombolisis intravenosa + trombectomía mecánica intraarterial.					
Comparación	Trombolisis intravenosa.					
Desenlaces	**Efecto relativo (IC 95%) -- Estudios/ pacientes**	**Efecto absoluto estimado***			**Certeza de la evidencia (GRADE)**	**Mensajes clave en términos sencillos**
		Trombolisis	**Trombolisis + trombectomía**	**Diferencia (IC 95%)**		
Mortalidad	RR 0,86 (0,72 a 1,03) -- 9 ensayos/ 2507 personas [38-41, 43-47]	184 por 1000	158 por 1000	Diferencia: 26 menos (51 menos a 6 más)	⊕⊕◯◯[1,2] Baja	Realizar trombolisis junto a trombectomía comparado a sólo realizar trombolisis podría disminuir la mortalidad, pero la certeza de la evidencia es baja.
Funcionalidad (mRS 0 a 2**)	RR 1,45 (1,25 a 1,69) -- 9 ensayos/ 2470 personas [38-41, 43-47]	322 por 1000	467 por 1000	Diferencia: 145 más (81 a 222 más)	⊕⊕⊕◯[1,3] Moderada	Realizar trombolisis junto a trombectomía comparado a sólo realizar trombolisis podría aumentar la funcionalidad, pero la certeza de la evidencia es baja.
Hemorragia intracraneal sintomática	RR 1,19 (0,83 a 1,71) -- 9 ensayos/ 2508 personas [38-41, 43-47]	44 por 1000	53 por 1000	Diferencia: 9 más (8 menos a 32 más)	⊕⊕◯◯[1,2] Baja	Realizar trombolisis junto a trombectomía comparado a sólo realizar trombolisis podría aumentar la hemorragia intracraneal sintomática, pero la certeza de la evidencia es baja.

IC 95%: Intervalo de confianza del 95% // RR: Riesgo relativo // GRADE: Grados de evidencia Grading of Recommendations Assessment, Development and Evaluation.

Modified Rankin Scale for Neurologic Disability**: Escala de 0 a 4 puntos, menos puntos es mejor. 0-2 es considerado como funcional y 3-4 con algún grado de limitación funcional.

* El **riesgo CON trombolisis** está basado en el riesgo del grupo control en los estudios. El **riesgo CON trombolisis + trombectomía** (y su intervalo de confianza) está calculado a partir del efecto relativo (y su intervalo de confianza).

[1] Se disminuyó un nivel de certeza de evidencia por riesgo de sesgo, ya que ninguno de los ensayos fue ciego para pacientes y participantes. A pesar de que los evaluadores de los desenlaces sí fueron ciegos, la importancia de cegar a todos los participantes de los ensayos clínicos radica en que no cegar a pacientes y tratantes puede llevar a tener seguimientos y cointervenciones diferentes dependiendo de la rama del estudio al pertenecen, alterando el resultado (sesgo de desempeño o performance bias). Además, las conclusiones por análisis por subgrupo con pocos estudios (9 en este caso) son muy limitadas y todos los ensayos presentaron la misma debilidad, por lo que no es posible comparar los resultados con un grupo de estudios sin este sesgo. Finalmente, 5 ensayos presentaron detención precoz por beneficio [36, 38, 39, 44, 45] y en 4 ensayos [36, 37, 40, 42] los grupos difieren en sus características basales, lo cual también podría actuar como confundente en los resultados de las intervenciones.

[2] Se disminuyó un nivel de certeza de evidencia por imprecisión, ya que cada extremo del intervalo de confianza conlleva a una decisión diferente.

[3] Si bien existe algún grado de inconsistencia, no se disminuyó la certeza de la evidencia por este factor ya que en buena parte proviene del ensayo IMS 3, que evaluó pacientes en quienes no se determinó previamente el tipo de vaso comprometido y dispositivo utilizado, lo cual no refleja la práctica actual.

Fecha de elaboración de la tabla: Noviembre, 2018.

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