SUBSECRETARÍA DE SALUD PÚBLICA
DIVISIÓN DE PLANIFICACIÓN SANITARIA
DEPARTAMENTO EVALUACIÓN DE TECNOLOGÍAS SANITARIAS Y SALUD BASADA EN EVIDENCIA

RECOMENDACIÓN DE DIAGNÓSTICO
INFORME DE BÚSQUEDA Y SÍNTESIS DE EVIDENCIA DE EFECTOS DESEABLES E INDESEABLES
Guía de Práctica Clínica de Cáncer cervicouterino - 2019

A. PREGUNTA CLÍNICA

En mujeres con cáncer cervicouterino invasor incluyendo IB2 (FIGO 2018) ¿Se debe "realizar estudio ganglionar centinela" en comparación a "linfadenectomía"?

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

Población: Mujeres con cáncer cervicouterino invasor incluyendo IB2 (FIGO 2018).
Intervención: Realizar estudio ganglionar centinela.
Comparación: Linfadenectomía.
Desenlace (outcome): Impacto diagnóstico, exactitud diagnóstica.

B. MÉTODOS

Se realizó una búsqueda general de revisiones sistemáticas sobre cáncer cervicouterino (ver Anexo 1: estrategia de búsqueda). 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; PsyclNFO; 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.

En las preguntas que comparan tests diagnósticos, se considera necesario distinguir dos enfoques para abordarlas: *impacto diagnóstico* y *exactitud diagnóstica*. Se estableció priorizar estudios que evaluarán el *impacto diagnóstico del test*, es decir aquellos que comparan los resultados en salud de los pacientes diagnosticados/tratados en función a los resultados de un test. En caso de no encontrar este tipo de

estudios, se utilizan estudios que evalúan la *exactitud diagnóstica del test*, es decir aquellos que miden qué tan bien el test clasifica a los pacientes respecto a si tienen o no una condición.[1]

Se seleccionaron las revisiones sistemáticas (y los estudios incluidos en éstas) correspondientes a la temática y se clasificaron en función de las preguntas a las que daban respuesta. 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. RESULTADOS

Resumen de la evidencia identificada

Se buscaron revisiones sistemáticas que analizan estudios en mujeres con cáncer cervicouterino en etapa operable, en los cuales a un grupo se le realiza evaluación con estudio ganglionar quirúrgico de cualquier tipo, contra un grupo en que no se realiza, midiendo desenlaces clínicos (impacto diagnóstico; evidencia directa). No se identificaron estudios de impacto diagnóstico, por lo cual se amplió la búsqueda a exactitud diagnóstica del test.
Se identificaron 12 revisiones sistemáticas que incluyeron 116 estudios primarios de exactitud diagnóstica. Para más detalle ver "*Matriz de evidencia*"[2], en el siguiente enlace: Estudio ganglionar quirúrgico para etapificar el cáncer cervicouterino operable.

Tabla 1: Resumen de la evidencia identificada

Revisiones sistemáticas	12 [1-12]
Estudios primarios	1 ensayo aleatorizado [13] y 115 observacionales [14-128]

Selección de la evidencia

Se realizó un análisis de la matriz de evidencia, identificándose que todos las revisiones sistemáticas y estudios observacionales son relevantes, ya que abordan específicamente los componentes de la pregunta priorizada por el panel. El ensayo aleatorizado [13] se excluyó, ya que compara la exactitud diagnóstica de dos técnicas de ganglio centinela.

Estimador del efecto

Al analizar la evidencia identificada, se concluyó que existe una revisión sistemática [4] que:

1. Incluye la mayoría de los estudios posiblemente relevantes, ya que si bien no identifica al total de estudios, la incorporación de estos no cambia significativamente los resultados.
2. Entrega un estimador agregado del efecto (metanálisis) para los desenlaces de interés.

[1] Schünemann HJ, Schünemann AHJ, Oxman AD, Brozek J, Glasziou P, Jaeschke R, et al. Grading quality of evidence and strength of recommendations for diagnostic tests and strategies. BMJ [Internet]. 2008 May 17 [cited 2018 Aug 1];336(7653):1106–10.

[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.

Por lo que se decidió utilizar su información para construir la tabla de resumen de resultados. Solo 46 estudios presentaron datos suficientes para ser incorporados a un metanálisis, de acuerdo a la revisión sistemática analizada.

Metanálisis

Exactitud diagnóstica

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value
Schwendinger 2006	0.830	0.695	0.913	4.081	0.000
Lantzsch 2001	0.929	0.630	0.990	2.472	0.013
Van Dam 2003	0.840	0.643	0.939	3.040	0.002
dos Reis 2007	0.917	0.587	0.988	2.296	0.022
Vieira 2009	0.839	0.719	0.914	4.543	0.000
Vieira 2004	0.627	0.488	0.748	1.800	0.072
Silva 2005	0.929	0.825	0.973	4.943	0.000
Khinkova 2005	0.519	0.433	0.604	0.440	0.660
Belhocine 2013	0.938	0.461	0.996	1.854	0.064
Plante 2013	0.971	0.664	0.998	2.436	0.015
Roy 2011	0.991	0.963	0.998	6.544	0.000
Hauspy 2007	0.974	0.839	0.996	3.591	0.000
Li 2004	0.964	0.786	0.995	3.236	0.001
Yuan 2007	0.827	0.729	0.895	5.328	0.000
Zhu 2011	0.950	0.874	0.981	5.740	0.000
Du 2011	0.941	0.854	0.978	5.380	0.000
Sheng 2004	0.826	0.618	0.933	2.832	0.005
Wang 2004	0.700	0.473	0.859	1.736	0.082
Zhang 2014	0.875	0.760	0.939	4.816	0.000
Liu 2013	0.952	0.729	0.993	2.924	0.003
Klat 2012	0.941	0.899	0.966	9.318	0.000
Rob 2005	0.874	0.818	0.915	8.698	0.000
Holub 2004	0.938	0.461	0.996	1.854	0.064
Bournaud 2013	0.976	0.849	0.997	3.669	0.000
Lambaudie 2003	0.917	0.587	0.988	2.296	0.022
Marchiole` 2004	0.983	0.783	0.999	2.859	0.004
Lecuru 2011	0.978	0.935	0.993	6.534	0.000
Bats 2008	0.886	0.788	0.942	5.451	0.000
Lelievre 2004	0.750	0.377	0.937	1.346	0.178
Klapdor 2014	0.941	0.833	0.981	4.659	0.000
Altgassen 2008	0.897	0.869	0.919	15.975	0.000
Fotiou 2010	0.929	0.801	0.977	4.281	0.000
Somashekhar 2012	0.976	0.713	0.999	2.594	0.009
Rajaram 2010	0.889	0.500	0.985	1.961	0.050
Angioli 2005	0.703	0.539	0.827	2.392	0.017
Yamashita 2009	0.862	0.748	0.929	4.813	0.000
Ogawa 2010	0.878	0.788	0.933	5.850	0.000
Furukawa 2010	0.833	0.523	0.958	2.078	0.038
Kato 2011	0.980	0.871	0.997	3.853	0.000
Niikura 2012	0.986	0.813	0.999	2.993	0.003
Niikura 2004	0.900	0.676	0.975	2.948	0.003
Seong 2007	0.573	0.469	0.671	1.373	0.170
Lee 2007	0.991	0.877	0.999	3.341	0.001
Maffuz 2010	0.867	0.595	0.966	2.464	0.014
Acharya 2009	0.800	0.621	0.907	3.037	0.002
Sniadecki 2014	0.714	0.327	0.928	1.095	0.273
Wydra 2006	0.840	0.755	0.900	6.079	0.000
Basta 2005	0.962	0.859	0.990	4.464	0.000
Di Stefano 2005	0.900	0.781	0.958	4.661	0.000
Diaz-Feijoo 2011	0.978	0.732	0.999	2.662	0.008
Fusté 2007	0.833	0.369	0.977	1.469	0.142
Diaz-Feijoo 2008	0.990	0.862	0.999	3.247	0.001
Vidal-Sicart 2009	0.900	0.781	0.958	4.661	0.000
Darlin 2010	0.895	0.821	0.941	6.732	0.000
Lin 2005	0.984	0.789	0.999	2.883	0.004
Verheijen 2000	0.800	0.459	0.950	1.754	0.080
Crane 2011	0.600	0.297	0.842	0.628	0.530
van der Vorst 2011	0.950	0.525	0.997	2.029	0.042
Schaafsma 2012	0.778	0.535	0.914	2.210	0.027
Hoogendam 2013	0.935	0.840	0.976	5.173	0.000
Kara 2008	0.985	0.799	0.999	2.929	0.003
Devaja 2012	0.977	0.912	0.994	5.224	0.000
Cormier 2011	0.934	0.874	0.967	7.264	0.000
Fader 2008	0.921	0.782	0.974	4.084	0.000
O'Boyle 2000	0.600	0.380	0.786	0.888	0.374
Levenback 2002	0.988	0.829	0.999	3.070	0.002
Frumovitz 2012	0.850	0.624	0.951	2.770	0.006
Echt 1999	0.154	0.039	0.451	-2.218	0.027
Kushner 2007	0.976	0.713	0.999	2.594	0.009
Shiravani 2014	0.800	0.459	0.950	1.754	0.080
	0.892	0.863	0.916	15.157	0.000

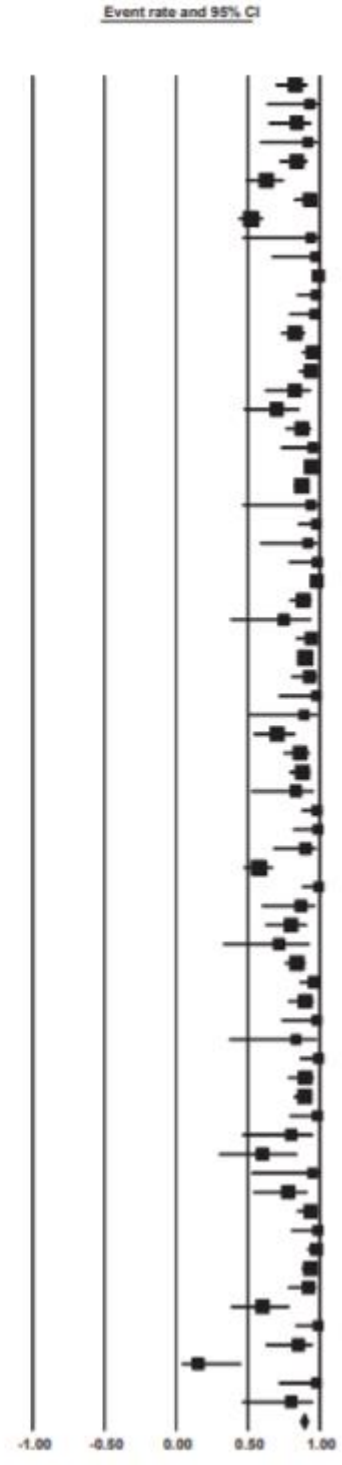

Figure 2. Forest plot of detection rate pooling.

Tabla de Resumen de Resultados (Summary of Findings)

REALIZAR ESTUDIO GANGLIONAR CENTINELA COMPARADO CON LINFADENECTOMÍA PARA CÁNCER CERVICOUTERINO INVASOR INCLUYENDO IB2.			
Pacientes	Mujeres con cáncer cervicouterino invasor incluyendo IB2 (FIGO 2018).		
Test	Realizar estudio ganglionar centinela.		
Comparación	Linfadenectomía.		
Impacto diagnóstico			
Desenlaces	**Efecto**		
Morbilidad o mortalidad	No se identificaron estudios evaluando el impacto, por lo que el desenlace se estimó en base a la exactitud diagnóstica del test, y de las consecuencias esperadas a partir de cada resultado.		
Desenlaces	Prevalencia hipotética 18%*	**Certeza de la evidencia (GRADE)****	**Mensajes clave en términos sencillos**
Sensibilidad: 89,2% (IC 95% de 86,3 a 91,6%). Especificidad: No calculable*** 46 estudios en una revisión sistemática [4] (No se reporta cantidad total de pacientes). Población hipotética de 1000 personas con 200 con compromiso ganglionar y 800 sin compromiso ganglionar.			
Pacientes con compromiso ganglionar (verdaderos positivos)	178 (173 a 183)	⨁⨁◯◯[1] Baja	En una población de 1000 pacientes con cáncer cervicouterino IB2 que requieren evaluación de compromiso ganglionar, realizar ganglio centinela podría diagnosticar correctamente a 178 pacientes de los 200 que realmente tienen compromiso ganglionar, pero la certeza de la evidencia es baja.
Pacientes incorrectamente clasificados de no tener compromiso ganglionar (falsos negativos)	22 (17 a 27)	⨁⨁◯◯[1] Baja	En una población de 1000 pacientes con cáncer cervicouterino IB2 que requieren evaluación de compromiso ganglionar, realizar ganglio centinela podría diagnosticar incorrectamente como sin compromiso ganglionar a 22 pacientes de los 200 que realmente tienen compromiso ganglionar, pero la certeza de la evidencia es baja.
Pacientes sin compromiso ganglionar (verdaderos negativos)	No calculable	--	--
Pacientes clasificados incorrectamente de tener compromiso ganglionar (falsos positivos)	No calculable	--	--

IC: Intervalo de confianza del 95%.
GRADE: grados de evidencia del GRADE Working Group.
*La prevalencia corresponde al promedio de prevalencia de los estudios de la revisión sistemática [129].
** Certeza de exactitud diagnóstica.
***La linfadenectomía (gold standard) solo se realizó en los pacientes con ganglio centinela positivo (por temas éticos). Por lo cual no es posible calcular la especificidad junto con los verdaderos negativos ni falsos positivos.
[1] Se disminuyó dos niveles de certeza de evidencia ya que el gold standard sólo se realizó en pacientes con ganglio centinela positivo.
Fecha de elaboración de la tabla: Septiembre, 2019.

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ANEXO 1: ESTRATEGIA DE BÚSQUEDA

#1 cervical* OR cervix*

#2 cancer* OR neoplas* OR tumor* OR tumour* OR malignan* OR metasta* OR nodul* OR polyp* OR cyst* OR adenocarcinoma* OR carcinoma* OR oncolog* OR dysplasia*

#3 sentinel* OR slnb OR sln OR snb OR "sn biopsy"

#4 #1 AND #2 AND #3