

**COMUNICAR LOS
RESULTADOS NEGATIVOS,
FUNDAMENTAL PARA EL
PROGRESO DE LA
RADIOLOGÍA**

*Ángeles Franco López**

*Gabriel Fernández Pérez***

***Hospitales de Torrevieja y Vinalopó (Alicante)**

****Hospital Rio Ortega de Valladolid**

OBJETIVOS

- 1. Dar a conocer la importancia que en el mundo científico tiene la publicación de los resultados negativos**
- 2. Recalcar la importancia que en el ámbito de la radiología supone la «no realización» de pruebas de escaso impacto clínico**

REVISIÓN DEL TEMA

- **Definición de estudio negativo**
- **Impacto en el mundo científico**
- **Impacto en la radiología**

¿QUE ES UN ESTUDIO NEGATIVO?

Estudio realizado con:

- **Un protocolo adecuado**
- **Potencia necesaria**
- **Intentando demostrar la superioridad de un procedimiento**
- **No lo consigue**

IMPACTO DEL ESTUDIO NEGATIVO

La ocultación de este tipo de estudios obliga a su repetición, lo que supone pérdida de tiempo y despilfarro de dinero

- **Son estudios verdaderamente importantes**
- **Gran impacto en el conocimiento**
- **Abonan el terreno para investigaciones posteriores**

PROBLEMÁTICA DE LOS ESTUDIOS NEGATIVOS

- **No hay cultura de su publicación**
- **Los resultados negativos son esenciales en la construcción del edificio de la ciencia ya que nos orientan hacia «donde no hay que trabajar»**

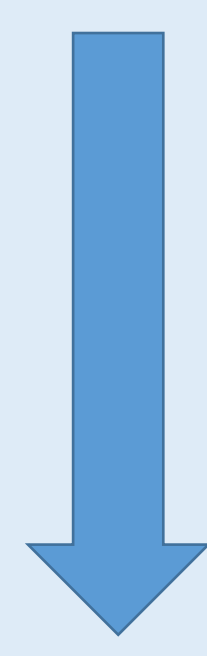
NEGATIVO ES POSITIVO

- **La comunidad científica los ignora pero suponen una gran pérdida de recursos**
- **La publicación de los mismos es ahora un requerimiento de CONSORT (estándares de publicación de los ensayos clínicos)**

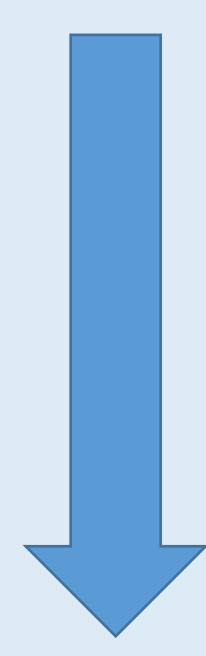


Este es el comportamiento de las revistas en las que solamente los experimentos con resultado positivo terminan siendo material publicado

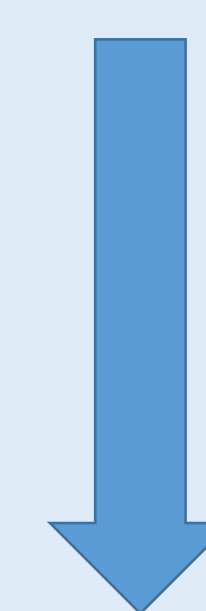
HIPÓTESIS



EXPERIMENTOS



RESULTADOS



PUBLICACIÓN

**Aproximación más
neutral que evita la
repetición de
experimentos**

REVISTAS FOCALIZADAS EN LOS RESULTADOS NEGATIVOS (2015)

All Results Journals (Chem, Nano, Biol, Phys)*	SAC SIS	http://arjournals.com/ (2010)
Journal of Articles in Support of the Null Hypothesis*	Reysen Group	http://www.jasnh.com/ (2002)
Journal of Errology	Unknown	http://www.bioflukes.com/ (unknown; discontinued; site down)
Journal of Interesting Negative Results	Unknown	http://jinr.site.uottawa.ca/ (2008; discontinued)
Journal of Negative Observations in Genetic Oncology	Unknown	http://www.path.jhu.edu/NOGO (1997; discontinued; site down)
Journal of Negative Results in BioMedicine*	BioMed Central (Springer Science) ^a	http://www.jnrbm.com/ (2002)
Journal of Negative Results – Ecology and Evolutionary Biology	JNR-EEB.org	http://jnr-eeb.org/index.php/jnr (2002; discontinued)
Journal of Pharmaceutical Negative Results*	Wolters Kluwer	http://www.pnrjournal.com/ (2010)
Nature Negative Results section*	Nature Publishing Group	http://www.nature.com/jcbfm/ (2010) ^b
The Journal of Spurious Correlations	International Sociology Association	http://www.jspurc.org/intro2.htm (2005; discontinued)
The International Journal of Negative & Null Results	International Journal Network	http://www.journalnetwork.org/
The Null Journal	Unknown	http://null-journal.com/ (2009; discontinued)
University of Colorado Database of Negative Results	University of Colorado	https://sites.google.com/site/cujonr/ (2011; discontinued)

REVISTAS FOCALIZADAS EN LOS RESULTADOS NEGATIVOS

- De las 13 solo persisten cinco
- En 2016 ha aparecido una nueva en español: **Journal of Negative and no Positive Reports (JONNPR)**
<http://www.jonnpr.com/>



seram 34

Sociedad Española de Radiología Médica

Congreso Nacional

PAMPLONA 24 MAYO
27 2018

Palacio de Congresos Baluarte

23 mayo Cursos Precongreso

NEGATIVO ES POSITIVO



The American Journal of Gastroenterology ha hecho un número monográfico sobre los «resultados negativos»

RADIOLOGÍA

CONSIDERACIONES

- En febrero de 2006 se publicó el informe **ENEAS**, que estudió los efectos adversos ligados a la hospitalización en 24 hospitales del Sistema Nacional de Salud.
- Este informe mostró que la tercera causa de efectos adversos (25%) eran los relacionados con problemas técnicos durante la realización de un procedimiento.
- Hasta el 42,8 % de los efectos adversos se consideró evitable. Por tanto, estos efectos adversos no solo pueden producir daño al paciente, sino que ocasionan un mayor gasto al Sistema Sanitario, por el incremento de estancias, pruebas diagnósticas y tratamientos que en muchos casos podrían haberse evitado.

La SERAM ha realizado esta publicación con exploraciones que no se deben hacer

Recomendaciones de "no hacer"

Para médicos prescriptores, radiólogos y pacientes



seRam
Sociedad Española de Radiología Médica

**1º MUERTE POR
OBSOLESCENCIA**

2º ESTUDIO NO ADECUADO

**3º ÁREAS DE
INCERTIDUMBRE**

EJEMPLOS

- **1º MUERTE POR OBSOLESCENCIA:**

Estudios que han sido sustituidos por otras técnicas por diferentes motivos. Mayor sensibilidad y especificidad de otras técnicas

- **2º ESTUDIO NO ADECUADO**

La realización de los mismos no es coste-eficaz: consumo de recursos, dosis de radiación y gran número de falsos positivos

- **3º ÁREAS DE INCERTIDUMBRE**

Cambios en las guías; se necesitan más estudios

MUERTE POR OBSOLESCENCIA

E. Stephen Amis, Jr, MD

Epitaph for the Urogram¹

The excretory urogram is terminally ill. It survives only because of clinicians and radiologists who do not fully appreciate that more accurate delineation of the urinary tract can be gained with other techniques. Over my 31 years of learning and practicing urology (initially) and radiology, the time-honored urogram served well for demonstrating the anatomy and, to a more limited degree, the function of the urinary tract. It is now time to move on to different techniques.

The advent of cross-sectional imaging methods and their increasing sophistication over the quarter century of their existence has prompted urologists to question the continued effectiveness of the urogram. Pollack and Banner (1) wrote in 1985, concluding that the technique was useful for many urinary tract conditions and that the time had not yet arrived to write its epitaph. In 1992, Choyke (2) questioned whether rumors of the death of the urogram were premature. His opinion was written in response to a report on the combination of ultrasonography and kidneys, ureter, bladder, or KUB, radiography as essentially equivalent to excretory urography with regard to the diagnosis of acute renal colic.

Choyke concluded that urography remained the examination of choice. This conclusion, however, came into question in 1995 with publication of the seminal article by Smith and colleagues (3), who compared nonenhanced computed tomography (CT) and intravenous urography for the examination of patients with acute flank pain. They eliminated the possible presence of ureteral stone as one of the two major remaining indications for excretory urography, the other being the work-up in patients with hematuria.

Over the past 4 years, the results of multiple studies have confirmed the superiority of nonenhanced helical CT for help in detecting urinary tract calculi. The single remaining substantive issue with regard to calculi, which caused many urologists to favor urography over CT, was the inability of nonenhanced CT to demonstrate the degree of obstruction. This issue has now been resolved by Boridy and colleagues (4) who, in the current issue of *Radiology*, show that the extent of perinephric edema seen on nonenhanced helical CT images can be used to predict the degree of ureteral obstruction in patients with ureterolithiasis, with an accuracy of 94%.

Writing from the same institution as Boridy et al a year earlier, investigators (5) were alerted to this potentially useful sign when they found that perinephric stranding was more prominent in patients whose stones passed spontaneously. They

the findings of Boridy et al. In 1996, Regan and colleagues (6) reported that magnetic resonance urography demonstrated perirenal fluid in 20 (87%) of 23 acutely obstructed kidneys.

Despite these findings, CT has not yet realized its full potential. A message from the Society of Uroradiology in 1998 regarding the future directions of imaging research suggested that much of the information available at CT (eg, stone size, attenuation, shape, location) is not yet fully used (7). These data could be integrated into treatment modalities such as extracorporeal shockwave lithotripsy, so that CT could be used to aid not only in diagnosis but also in treatment. Further, virtual endoscopy will most likely allow a "fly-through" view of the ureter and help differentiate stones from phleboliths and even help detect small urethelial neoplasms.

Some results have already been reported (8,9) on the capability of CT for in vitro determination of stone composition. These results indicate that it may eventually be possible to differentiate among uric acid, struvite, and calcium oxalate stones (9). Although almost all urinary tract calculi, regardless of composition, are visible at nonenhanced CT, there is one group of patients in whom the obstructing calculus is not visible: in approximately 4% of patients infected with human immunodeficiency virus (HIV) who are undergoing indinavir therapy, a commonly used HIV-protease inhibitor, precipitated crystals can form

Index terms:
Editorials
Kidney, CT, 81.12113, 81.12115
Ureter, calculi, 82.811
Ureter, CT, 82.12111, 82.12115

Colon Imaging in Radiology Departments in 2008: Goodbye to the Routine Double Contrast Barium Enema

Giles Stevenson, BM, BCh, FRCP, FRCR, FRCPC

Computed tomography colonography (CTC), or virtual colonoscopy, is the 'brainchild of Dr David Vining,¹ who developed the technique in 1993 and presented it to an astonished audience at the annual meeting of the Society of Gastrointestinal Radiologists in 1994. After 13 years of development, the technology has caught up with the concept, and it is now a robust tool for clinical examination of the colon.

The article by Dr Margaret Fraser-Hill and colleagues² in this issue of the *Journal* summarizes the current abilities of CTC, and discusses its role in screening for colorectal carcinoma and adenoma in a Canadian context. It is clear from the literature that the sensitivity of CTC for detection of cancer is as good as, or slightly better than, optical colonoscopy (OC).³⁻⁴ Barium enema quality is slipping,⁵ except perhaps where technologists have been trained and are supported by radiologists, mainly in the United Kingdom,⁶ and only a few reports from specialist gastrointestinal (GI) radiology centres^{7,8} have in the past reported cancer detection rates competitive with OC or CTC. In general, the double contrast barium enema (DCBE) has to be combined with flexible sigmoidoscopy to have the same sensitivity as colonoscopy for cancer (96.7%).¹¹ However, in screening, cancer is not the prime target, as the mortality reduction from earlier detection of a few cancers by screening is trivial, compared with that achieved by removal of large numbers of advanced adenomas.

Professor Emeritus, Department of Radiology, McMaster University, Hamilton, ON, Computed Tomography Colonography Project, Vancouver Island Health Authority, Victoria, BC

Address for correspondence: Dr G Stevenson, 2723 Mount Stephen Avenue, Victoria, BC V8T 3L7; gste@shaw.ca

Received February 15, 2008

Accepted February 15, 2008

Can Assoc Radiol J 2008;59(4):174-182

Key Words: computed tomography colonography; virtual colonoscopy; barium enema; colorectal cancer screening; colonic adenomas



Actas Urológicas Españolas

www.elsevier.es/actasufo



Artículo especial

La urografía intravenosa ha muerto, ¡viva la tomografía computarizada!

Á. Franco*, M. Tomás y A. Alonso-Burgos

Servicio de Radiología, Fundación Jiménez Díaz, Madrid, España

INFORMACIÓN DEL ARTÍCULO

Historia del artículo:

Recibido el 20 de abril de 2010

Aceptado el 27 de abril de 2010

On-line el 19 de junio de 2010

Palabras clave:

Urografía

Tomografía computarizada

Hematuria

Litiasis

Neofeocitosis

RESUMEN

Durante la última mitad del siglo *xx* se han producido cambios muy importantes en el campo de la imagen genitourinaria, de forma que para la mayor parte de las históricas indicaciones de la urografía intravenosa la tomografía computarizada (TC) es ahora la técnica de elección.

El objetivo de este trabajo es realizar una actualización del correcto uso de las pruebas de imagen, con especial enfoque en la TC, en la patología urológica del adulto revisando las entidades más frecuentes: litiasis, hematuria, infecciones, tumores, controles de cirugía y pielectasia.

Hacemos un breve recorrido histórico por las pruebas de imagen utilizadas en urología a través de los años, haciendo hincapié en sus fundamentos físicos.

En la segunda parte revisamos las diferentes patologías urológicas y el papel que desempeñan la radiografía simple, la ecografía, la TC y la resonancia magnética, analizando su sensibilidad y su especificidad.

Por último, hacemos una breve reflexión acerca de las dosis de radiación de los diferentes métodos radiológicos.

© 2010 AEU. Publicado por Elsevier España, S.L. Todos los derechos reservados.

ESTUDIOS INADECUADOS

Un estudio de imagen apropiado es aquel en el que el aumento de información que se espera obtener, combinado con el juicio clínico, excede las consecuencias negativas esperadas* por un amplio margen para cada indicación específica, de manera que el procedimiento diagnóstico se considera una aproximación aceptable y razonable.

*Las expectativas negativas incluyen el riesgo del procedimiento y el impacto negativo de un test con bajo rendimiento tales como retrasos diagnósticos (falsos negativos) o diagnósticos inapropiados (falsos positivos)

seram Recomendaciones de "no hacer"

NO
hacer

Pruebas de imagen para detectar metástasis en pacientes con cáncer de mama y asintomáticas

El cáncer de mama es el cáncer más frecuente en la mujer. Cada año se diagnostican un número importante de cánceres de mama, y aproximadamente el 60-80% de los mismos, y gracias a los programas de detección precoz, se encuentran en estadios iniciales (carcinoma in situ o carcinomas invasivos estadios I y II).

La existencia de metástasis a distancia en mujeres con cáncer de mama en estadios iniciales y asintomáticas es muy improbable.

La realización de pruebas diagnósticas para descartar metástasis a distancia en este grupo de mujeres ocasiona sobrecarga importante en los servicios de imagen de los centros, y resta oportunidad a pacientes que se beneficiarían más de dichas pruebas. Suponen un importante impacto económico para los centros, ya que la mayoría de ellas necesitan, además, la utilización de contrastes intravenosos.

Por otra parte, la realización de estas pruebas conlleva retrasos en la aplicación del tratamiento, ansiedad en las pacientes, posibles falsos positivos, realización de pruebas invasivas innecesarias como biopsias, sobret ratamiento, aumento de la radiación sobre la paciente, etc.

Bibliografía

Breast Cancer Quality Standard. Nice Quality Standard 12. 2011.

Carlson RW, Allrod DC, Anderson BO et al. Invasive breast Cancer. *J Natl Compr. Canc Netw* 2011; 9: 135-222.

ASCO (American Society of Clinical oncology). *Choosing wisely*. Consumer Reports Health 2013.

NO ADECUADO

INCERTIDUMBRE

Residual Thrombosis on Ultrasonography to Guide the Duration of Anticoagulation in Patients With Deep Venous Thrombosis: A Randomized Trial

Prandoni, Paolo, MD, PhD; Prins, Martin H, MD, PhD; Lensing, Antonie WA, MD, PhD; Ghirarduzzi, Angelo, MD; Ageno, Walter, MD; et al. *Annals of Internal Medicine*, Philadelphia Tomo 150, N.º 9, (May 5, 2009): 577.

Annals of Internal Medicine

Resumen/detalles

Mostrar entradas duplicadas de otras bases de datos

Resumen Traducir

Ocultar subrayado

Prandoni et al assess whether tailoring the duration of anticoagulation on the basis of the persistence of residual thrombi on ultrasonography reduces the rate of recurrent venous thromboembolism (VTE) compared with the administration of conventional fixed-duration treatment in adults with proximal deep venous thrombosis (DVT). Patients were randomly assigned (stratified by center and secondary vs. unprovoked DVT by using a computer-generated list that was accessible only to a trial nurse) to fixed-duration anticoagulation (no further anticoagulation for secondary thrombosis and an extra 3 months for unprovoked thrombosis) or flexible-duration, ultrasonography-guided anticoagulation (no further anticoagulation in patients with recanalized veins and continued anticoagulation in all other patients for up to 9 months for secondary DVT and up to 21 months for unprovoked thrombosis). They conclude that tailoring the duration of anticoagulation on the basis of ultrasonography findings reduces the rate of recurrent VTE in adults with proximal DVT.

A raíz de diferentes publicaciones, una de las más conocidas, la que figura en la imagen, es una práctica frecuente en algunos hospitales de nuestro entorno: la realización de controles de imagen de TEP y TVP (TCMD y doppler)

INCERTIDUMBRE

Es una fuente de numerosas peticiones de TCMD y de Doppler de Miembros inferiores no validadas :

- En el caso del TEP no aconsejado por ninguna guía
 - En la TVP habría que individualizar cada caso
- Consumo de recursos y aumento de la dosis de radiación y contraste no refrendada por la medicina basada en la evidencia (MBE)

Revisión sistemática: máximo nivel de evidencia

Research Article

A Systematic Review of the Utility of Residual Vein Obstruction Studies in Primary and Secondary Venous Thrombosis

Murali Janakiram,^{1,2} Matthew Sullivan,² Marina Shcherba,^{1,2}
Shuang Guo,² and Henny H. Billett^{1,2}

¹ Division of Hematology, Montefiore Medical Center and the Albert Einstein College of Medicine, 341 Wayne Avenue, Ground Floor, Bronx, NY 10467, USA

² Department of Medicine, Montefiore Medical Center and the Albert Einstein College of Medicine, 341 Wayne Avenue, Ground Floor, Bronx, NY 10467, USA

Correspondence should be addressed to Murali Janakiram; mjanakir06@gmail.com

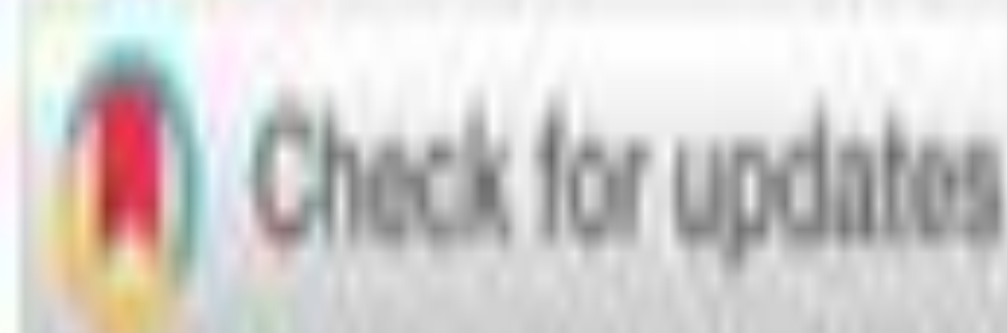
Received 20 June 2013; Revised 18 September 2013; Accepted 25 September 2013

Academic Editor: Domenico Prisco

Copyright © 2013 Murali Janakiram et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Background. Residual vein obstruction (RVO), the persistence of venous thrombosis with time and often after anticoagulation, may indicate a systemic prothrombotic condition. Prior studies have shown varying efficacy in using RVO as a risk factor for future venous thromboembolism (VTE) recurrence. **Methods.** To assess whether positive RVO imaging predicts recurrent VTE events, we performed a meta-analysis on studies in which patients with documented VTEs, anticoagulated for a minimum of 4 weeks, had repeat sonography to assess RVO and were subsequently followed for recurrent events. **Results.** Thirteen studies met inclusion criteria. 350 patient VTE events with 304 evaluable results were analyzed. The presence of RVO was associated with recurrence in all VTE (OR 1.9; 95% CI: 1.29, 2.89) and secondary VTE (OR 2.78; 95% CI: 1.41, 5.5) but not for primary VTE (OR 1.35; 95% CI: 0.67, 2.68). When cancer patients were eliminated from the secondary VTE group, there was no longer a significant association of RVO with VTE recurrence (OR 1.73; 95% CI: 0.81, 3.67) while in the subset of cancer patients, presence of RVO was associated with an increase in VTE recurrence risk (OR 3.14; 95% CI: 1.39, 6.65, $P < 0.006$). **Conclusions.** We conclude that the presence of RVO is associated with recurrence in secondary VTE but not in primary VTE and that association may be driven by the subset with cancer.

PROPOSICIÓN DE ALGORITMO



Review Article

VASCULAR
MEDICINE

Venous thromboembolism: Predicting recurrence and the need for extended anticoagulation

Vascular Medicine

2015, Vol. 20(3) 143-152

© The Author(s) 2015

Reprints and permissions:

sagepub.co.uk/journalsPermissions.nav

DOI: 10.1177/1368836315566428

vmj.sagepub.com

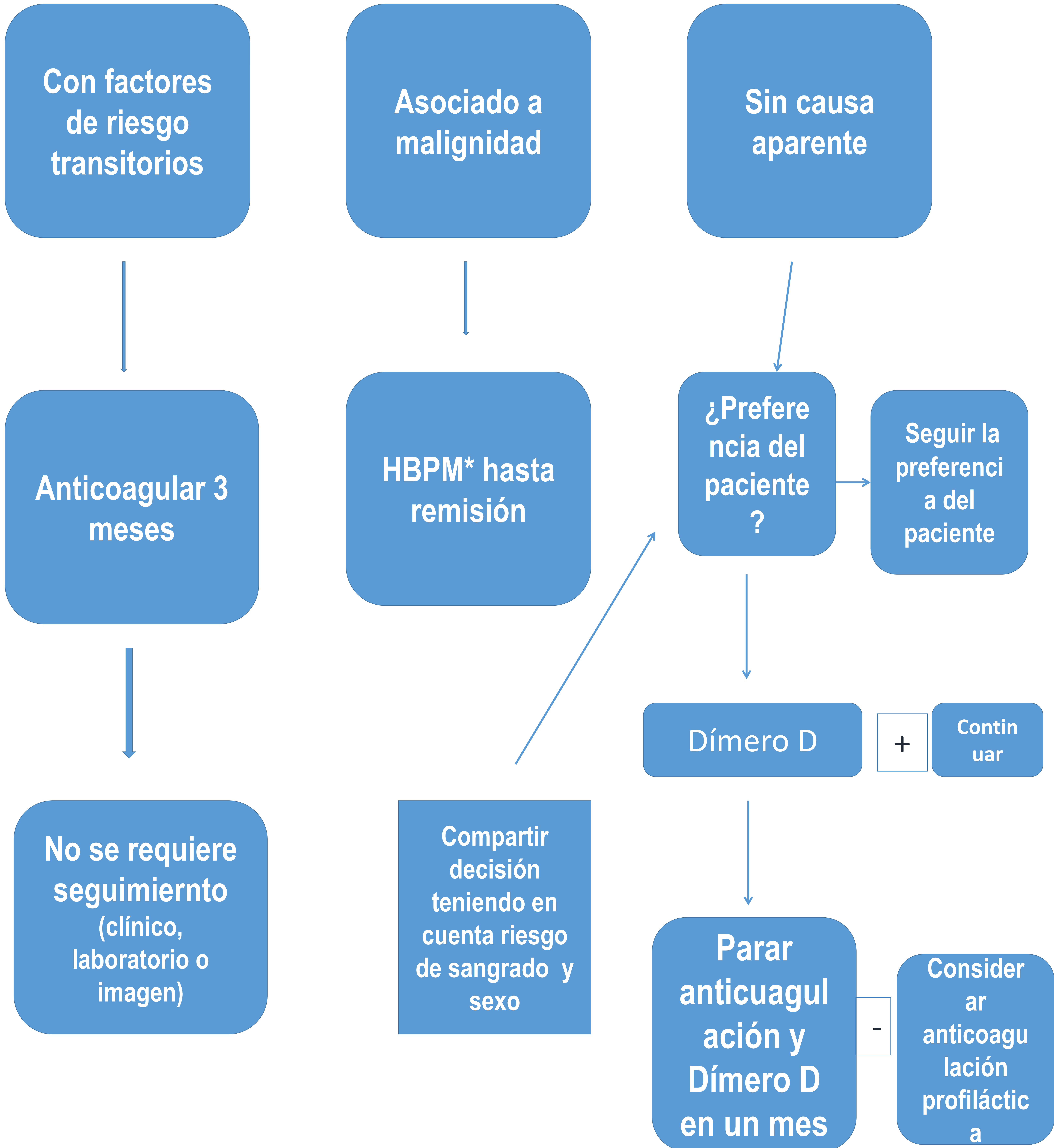


Geoffrey D Barnes, Yogendra Kanthi and James B Froehlich

Abstract

Initial treatment for venous thromboembolism (VTE) includes the acute and intermediate phases, usually lasting for 3 months. The choice to extend therapy beyond the initial 3-month window involves assessing a combination of risk factors for VTE recurrence and bleeding, along with weighing patient preferences. In some cases, such as VTE provoked by a reversible surgical risk factor, the recurrence risk is sufficiently low that most patients should not receive extended therapy. In other cases, such as VTE associated with malignancy, the recurrence risk is sufficiently high that treatment should be extended beyond the initial 3 months. However, a large number of patients fall into a grey zone where the decision on extended therapy is less clear-cut. In this review, we summarize the evidence for VTE recurrence risk and the role for extended anticoagulation given a variety of patient-specific factors and laboratory results. We also review the role of VTE risk prediction tools and provide a recommended algorithm for approaching the decision of extended anticoagulation therapy. Various agents available for extended VTE therapy, including warfarin, aspirin and the direct oral anticoagulant agents, are discussed.

**PRIMER
EPISODIO DE
TROMBOSIS
VENOSA
PROFUNDA**



*HBPM: Heparina de Bajo Peso Molecular

¿QUÉ PASA EN NUESTRO ENTORNO?

- **Debemos seguir las guías y revisarlas periódicamente**
- **Sería conveniente analizar nuestras series e identificar el tipo de estudios de los que no se derivan beneficios para el paciente ya que, aunque los defensores de la medicina basada en la evidencia critican la utilización de resultados observacionales como dogma, es muy importante conocer los datos de nuestras exploraciones**
- **Publicar estos resultados**

CAMBIO DE PARADIGMA

"FROM VOLUME TO VALUE"



CONCLUSIÓN

- **Los resultados negativos deben publicarse para que no sean repetidos con el consiguiente gasto de tiempo y dinero**
- **En el caso particular de la radiología debemos seguir las guías y revisar nuestras propias series para evaluar los resultados y conocer el valor de lo que hacemos**

BIBLIOGRAFÍA

- Martín-Peña G, Franco-López A. Resultados “no positivos” y resultados “negativos”: ¿Por qué cuentan?
JONNPR.2017;2(6):219-221. DOI: 10.19230/jonnpr.1429
- Smith GCS, Pell JP. Parachute use to prevent death and major trauma related to gravitational challenge:systematic review of randomised controlled trials. BMJ 2003;327;1459-1461.
doi:10.1136/bmj.327.7429.1459
- Franco-López A, Alonso-Burgos A. Exploraciones no recomendadas: la urografía intravenosa en el estudio del cólico nefrítico. JONNPR. 2017;2(3):107-114. DOI: 10.19230/jonnpr.1272
- Franco A, Tomas M, Alonso-Burgos A. Intravenous urography is dead. Long live computerized tomography! Actas Urol Esp 2010;34(9) :764–774
- Stephen Amis E, Jr. Epitaph for the Urogram. Radiology 1999; 213(3):639-640
- Barnes GD, Kanthi Y, Froehlich JB. Venous thromboembolism: Predicting recurrence and the need for extended anticoagulation. Vascular Medicine 2015, Vol. 20(2) 143–152
- Janakiram M, Sullivan M, Shcherba M, Guo S, Billett HH . A Systematic Review of the Utility of Residual Vein Obstruction Studies in Primary and Secondary Venous Thrombosis. Thrombosis Volume 2013, doi.org/10.1155/2013/247913
- <http://www.seram.es/modules.php?name=search> (entrada 12/03/2018)