

Vasectomy Litigation in Spain. The Importance of Post-vasectomy Pregnancy



TO THE EDITOR:

We would like to congratulate Blazek et al¹ for their thoughtful legal review of litigation in vasectomy cases. Nevertheless, great limitations have been reported at Westlaw legal database studies.

We compare Blazek's results with the Spanish setting, using the claims database of the Professional Liability Department of the Catalan Council of Physicians' Colleges, a potentially richer but smaller source of learning from error,² that collects information from both out-of-court and litigation cases from the main physician's professional liability insurance company in Catalonia (>27,000 physicians insured).

Blazek et al¹ note that the most commonly alleged breach of duty was negligence in postoperative care, followed by negligent surgical performance and negligence in performing informed consent. Pregnancy was the most commonly claimed damage.

In our sample, Urology ranks 10th among most frequently claimed specialties, with a mean frequency of 6.63 claims per year, a 19.84% of cases with an indemnity payment, and a mean payment of 39.231 euros.³ We identified 40 vasectomy-related claims between 1990 and 2012.⁴ Pregnancy was confirmed as the most commonly claimed damage (28 cases; 70%). In the rest of cases, alleged damage was infection (3 cases), hematoma (2 cases), need for surgical reoperation (2 cases), testicular atrophy (2 cases), chronic pain (2 cases), and 1 case of wrong site surgery (vasectomy instead of phimosis).

Pregnancy cases showed a high rate of pay-outs (42.86%) in our sample, as sometimes an obligation of results legally applies in this kind of procedures, even though guidelines may have been correctly followed. We found an even higher liability rate in cases of early spermogram (60%) and found no pay-outs in those cases in which 2 spermograms were made.

We found a specific informed consent document (ICD) for this procedure in only 10 cases (35.7%): two of those involved an evident documentation error, but the rest of them showed a lower rate of pay-outs (37.5%) than the no DCI/non-specific DCI group (50%). Nevertheless, it was far away from the 90% reported by Blazek et al, underlining important differences between countries in such an essential medico-legal issue.

Although our pay-out figures are lower from those reported at the US scenario (between 6000 and 65,000 euros), regarding these two specific important findings and their patient-safety relevance, we decided to go further than European and AUA Guidelines and recommend urologists to do a first spermogram not before 3 months post-vasectomy, to do a second spermogram even in cases of azoospermia and to highlight recanalization frequency at specific DCI. The potential effect of these kinds of medico-legal recommendations should be seen in the following years.

We would like to point out, that liability problems faced by urologists have elements of commonality between the United States and Spain, and the results hereby highlight that data emanating from different countries show similar trends besides contextual differences.⁵ An adequate communication with the patient, which includes a correct informed consent process, as well as a longer follow-up for longer, is, in our opinion, basic to improve clinical safety and reduce vasectomy claims.

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AUTHOR REPLY

We thank the authors for sharing the Catalan experience and how it both complements and differs from the US experience. We recognize the limitations of WestLaw which, nonetheless, is the most comprehensive dataset available in US. International data clearly confirms that



urologists are at considerably high medicolegal risk, and must take certain steps to minimize this. One aspect in particular that must be addressed is communication. Dealing with recovery and complications from procedures can be a lonely experience for patients. The basis of the patient-physician relationship is trust, and if a patient feels they cannot trust their physician after a bad outcome, they often feel the only place they can turn to is a lawyer. Trust is typically built through continued, honest communication regardless of whether information or outcomes are positive or negative. As listed in our paper, patient's who reported feeling rushed, ignored, received inadequate explanations, or perceived spending less time with their physician were two times more likely to sue.¹

Another aspect to consider is the importance of following data driven and proven guidelines in dictating therapy and follow-up. This is why we still recommend following the AUA and European guidelines with respect to pre-procedure counsel and a single negative PVSA, until such data suggests a second negative PVSA should be required.^{2,3} The counselling centers on both the common risks and rarer complications of recanalization and pregnancy. With only a ~50% return rate for a single PVSA, requiring 2 PVSAs has been shown to have even lower compliance rates while likely only confirming the initial negative PVSA.^{4,5} We believe this is why, in our study, pregnancy was associated with low indemnity payments, despite being the most commonly filed damage. These cases were often associated with negligence in

post-operative care, the liability of which can be mitigated by adhering to published guidelines. We thank the authors for their response and believe that Spanish data adds valuable information to an ongoing discussion as vasectomy continues to be offered and promoted world-wide.

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<https://doi.org/10.1016/j.urology.2019.06.046>

UROLOGY 132: 208–209, 2019. © 2019 Elsevier Inc.