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Association between reportable preventable adverse events and unfavorable decisions in medical malpractice claims involving obstetricians covered by FEPASDE Colombia 1999 to 2014. Case-control study

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Palabras clave: Obstetricia, Proceso Legal, Responsabilidad legal, Puntaje de propensión, Colombia

Asociación entre eventos reportables evitables y resultados desfavorables en los procesos de responsabilidad médica en obstetras apoderados por FEPASDE Colombia 1999 – 2014. Estudio de casos y controles

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Abstract

Introduction: Reportable, preventable events are potential causes for medical liability litigation. It is important to determine whether the occurrence of such events increases the risk of unfavorable legal or ethical decisions.

Objective: To assess the association between the occurrence of a reportable preventable event and unfavorable legal and ethical decisions in medical liability processes against obstetricians.

Materials and methods: Case-control study. *Population:* obstetricians affiliated to FEPASDE, with legal or ethical claims closed between 1999 and 2014 in Colombia. *Cases:* obstetricians with unfavorable judicial decision in malpractice claims. *Controls:* obstetricians with a favorable judicial decision. *Sample:* 322 subjects (64 cases, 258 controls). *Analysis:* variables concerning the obstetrician, the institution, the process, and the patient were measured. Bi-varied and multivariate analyses with a logistic regression model were conducted, using a propensity score or index.

Results: An association was identified between the occurrence of the reportable preventable event and an unfavorable ruling (OR=4,4; CI 95%: 2,23 – 8,76). *Other associated factors included:* private institution (OR=2,3 95% CI: 1,14–4,51), type of civil claim (OR=14,1 95% CI: 5,51–36,04), product diagnosis—demise (OR=3,1 95% CI: 1,64–5,94), history of other unfavorable proceedings (OR=2,3 95% CI: 1,27–4,06). Inadequacies in the prevention and medication therapy were associated with an unfavorable ruling ($P < 0.05$).

Conclusion: The presence of reportable preventable events is associated with an unfavorable legal or ethical decision in malpractice claims involving obstetricians. Inadequate patient management and poor functioning of the hospital care system provide opportunities for intervention to reduce the risk of an unfavorable legal or ethical decisions in malpractice claims.

Resumen

Introducción: Los eventos reportables prevenibles son potenciales causas de procesos de responsabilidad médica, es importante identificar si su ocurrencia incrementa el riesgo de decisiones judiciales o éticas desfavorables.

Objetivo: Evaluar la asociación entre la ocurrencia de un evento reportable prevenible y las decisiones judiciales y éticas desfavorables en procesos de responsabilidad médica contra obstetras.

Materiales y métodos: Estudio de casos y controles. *Población:* Obstetras vinculados a FEPASDE con procesos judiciales o éticos cerrados entre 1999 -2014 en Colombia. *Casos:* obstetras con decisión judicial desfavorable en procesos de responsabilidad médica. *Controles:* obstetras con una decisión judicial favorable. *Muestra:* 322 sujetos (64 casos, 258 controles). *Análisis:* se midieron variables del obstetra, la institución, del proceso, de la paciente. Análisis bi y multivariado con un

modelo de regresión logística y la utilización del puntaje o índice de propensión.

Resultados: Se encontró asociación entre la presencia de evento reportable prevenible y una decisión judicial desfavorable (OR=4,4; IC 95%: 2,23 – 8,76). Otros factores asociados fueron: institución privada (OR=2,3 IC 95%: 1,14 – 4,51), tipo de proceso civil (OR=14,1 IC 95%: 5,51 – 36,04), diagnóstico del producto - óbito (OR=3,1 IC 95%: 1,64 – 5,94), antecedente de otros procesos en contra (OR=2,3 IC 95%: 1,27 – 4,06). Deficiencias en la prevención y en el tratamiento con medicamentos se asociaron a una decisión judicial desfavorable ($p < 0.05$).

Conclusiones: La presencia de eventos reportables prevenibles se asocia a una decisión judicial o ética desfavorable en procesos de responsabilidad médica en Obstetras. Las deficiencias en el manejo del paciente y en funcionamiento del sistema de atención hospitalaria ofrecen oportunidades de intervención para reducir el riesgo de tener una decisión judicial o ética desfavorable en procesos de responsabilidad médica.

Introduction

Malpractice claims are filed when there is the perception that the performance of the medical practitioner was inappropriate, unskilled, or negligent.¹ There has been a growing number of claims in most countries between 1980 and 2010.^{2,3} In response to this situation, the surveillance systems of poor outcomes in healthcare have been improved.⁴ Nevertheless, there also has been a negative impact on healthcare costs, the practice of defensive medicine, and on the wellbeing of healthcare providers,^{5–7} the specialties with higher risk of being the target of malpractice claims are: emergency medicine, gynecology and obstetrics, anesthesiology and the surgical specialties.^{3,8}

One of the potential causes of malpractice claims are the poor outcomes in healthcare identified as reportable events (REs),^{9,10} or adverse events (AEs).¹¹ REs occur in 5% to 17% of hospitalized patients and 38% to 58% are preventable.^{11,12} In obstetrics, the frequency ranges from 3% to 12%, and 54% to 70% are preventable.^{13,14} REs exhibit a mortality around 2.8% to 4% per 1000 admissions.^{15,16} The methodology to study the frequency and classification of REs is clearly described,¹¹ as well as the research and analysis of associated factors.¹⁷

It is important to assess the factors associated with the judicial decisions in malpractice claims, particularly when the presence of preventable REs increases the risk of an unfavorable decision. Furthermore, there is a need to identified issues to be tackled through strategies aimed at reducing the risk of patients to experience a RE and the risk of doctors to be the target of a malpractice claims. Therefore, the purpose of this study is to assess whether there is an association between the occurrence of a reportable preventable event and an unfavorable legal or ethical decision.

Materials and methods

Design and population

Case-control study based on a cohort of legal or ethical processes between 1999 and 2014, against obstetricians affiliated to FEPASDE (Special Fund for Solidary Assistance during legal claims) associated with the Colombian society of Anesthesiology and Resuscitation (S.C.A.R.E.) in Colombia. Obstetricians with processes unrelated to healthcare services, associated with gynecological care, or with insufficient information were excluded. Cases were those proceedings which ended up in an unfavorable legal or ethical decision, including guilty verdict, admonishment, fine, conciliation, compensation, settlement, indemnity payment or disciplinary measure. The controls were litigations with a favorable ruling, including not guilty verdict, judgment for the defendant, lawsuit inadmissibility, revocation of guarantor inclusion, impleader repeal, falls under the statute of limitations or filed close.

Sampling and sample size

The cases were selected based on an unfavorable legal or ethical ruling. If an obstetrician had more than 1 malpractice claims, one of the processes was selected randomly. Controls were selected from the cohort using a simple random sampling. The size of the sample was estimated using OpenEpi, with an expected percentage of cases exposed to reportable preventable cases of 70% in the group of cases and of 50% among the control group, based on reported incidents of preventable REs in obstetric services.^{12,18,19} In addition, a case-control ratio of 1:4 was established, with a 95% confidence level and 80% power, for a total sample of 325 (65 cases and 260 controls).

Procedure

Based on FEPASDE's database, the malpractice claims involving obstetricians in the study period were identified, and the inclusion and exclusion criteria were verified. Data were collected regarding: Patient's baseline, healthcare management in each particular claim, the legal or ethical process, the obstetrician and the healthcare institution. The information was entered into a data collection form by 2 general practitioners previously trained in the management of the data base and medical records. Subsequently, the methodology validated in Colombia and developed by Baker et al for the identification and assessment of RE was followed.^{11,12} It was identified processes with screening events—defined as situations where unexpected events happened while providing patient care—that require further analysis or investigation¹¹ to determine whether a RE actually occurred with the mother or the fetus or neonate. Those

processes with an identified screening event were evaluated by an expert committee comprising 2 obstetric consultants from FEPASDE and 1 anesthesiologist with expertise in obstetric critical care, in order to decide whether there was a RE or not. The committee qualified a RE based on a numeric scale from 1 to 6. A rating of 1 to 3 associate the result with the underlying condition rather than with the health care management, while 4 to 6 associate the outcome with the health care management, rather than with the underlying condition. In terms of whether the outcomes were preventable, 1 to 3 rate the undesired result as non-preventable, while 4 to 6 is preventable. A cut point of 3 was used to rate the RE and to consider it preventable. The committee was not aware of the final litigation ruling and their opinion was based on the medical record and the information in the file. In addition, an analysis was conducted of the potential shortcomings in the health care management that led to reportable preventable events.

Variables

Obstetrician: age, gender, other ongoing malpractice claims. *Institution where care was delivered:* type of institution, location. *Process:* type of process (criminal, civil, ethical, administrative, and/or disciplinary). *Patient:* age, type of admission, gestational age, and time of occurrence of the event that led to the claim, newborn weight, diagnosis of the poor fetal outcome, neonatal demise, mode of delivery, type of discharge, type of health insurance (contributory, subsidized), presence of a reportable preventable or non-preventable event²⁰ and whether the RE occurred during delivery or was directly associated to it. The exposure was the presence of a reportable preventable event—defined as injuries inflicted as a result of health care management, which could have been prevented by following the best available management recommendations. The non-exposure group was defined as the absence of injury resulting from health care or the presence of a reportable unavoidable event, meaning that even if the best available management recommendations had been followed, the event could not have been prevented.¹¹

Analysis

The qualitative variables were expressed as absolute and relative frequencies, while the quantitative variables were expressed through means and standard deviation for the normal distribution variables, and medians and interquartile ranges for the non-normal distribution variables. The normality of the variables was evaluated using the Shapiro-Wilk test. The baseline characteristics of the cases and controls were compared using Mann-Whitney or Chi-square and Fisher exact tests, based on the type of variable. The association between reportable preventable

Table 1. Baseline characteristics of cases and controls undergoing malpractice claims covered by FEPASDE (S.C.A.R.E.) Colombia 1999 to 2014.

Variable	Cases n=64, n (%)	Controls n=258, n (%)	P
Exposure (RE preventable)	60 (93.8)	208 (80.6)	0.014*
Location			
Major city	29 (45.3)	110 (42.6)	0.651
Intermediate	27 (42.2)	122 (47.3)	
Rural	8 (12.5)	25 (9.7)	
Obstetrician gender (male)	51 (79.7)	196 (76.0)	0.621
Type of admission (emergency department)	51 (79.7)	222 (86.0)	0.176
Type of process			
Criminal	10 (15.6)	100 (38.8)	0.000*
Civil	22 (34.8)	15 (5.8)	
Ethical	24 (37.5)	115 (44.6)	
Administrative	8 (12.5)	28 (10.9)	
Affiliation (contributory)	48 (75.0)	147 (57.0)	0.038*
Type of discharge			
Improvement	49 (76.6)	196 (76.0)	0.336
Referred	10 (15.6)	29 (11.2)	
Demise	4 (6.3)	30 (11.6)	
Poor fetal outcome diagnosis			
Abortion	4 (6.3)	29 (11.2)	0.053
Demise	25 (39.1)	59 (22.9)	
Neonatal death	8 (12.5)	48 (18.6)	0.249
Mode of delivery (C-section)	34 (53.1)	130 (50.4)	1.000
Newborn birth weight, g [†]	3000 (2550–3500)	3180 (2670–3500)	0.218
Patient age, y [†]	30.5 (24.5–35.5)	27.0 (23.0–32.0)	0.014*
Gestational age, wk [†]	38.0 (33–39)	38.0 (34–40)	0.377
Claim related to delivery management (yes)	49 (76.6)	190 (73.6)	0.629
Age of physician, y [†]	41.0 (38–47)	41.0 (36.0–47.0)	0.531

RE=reportable event.

*Statistical significance ($P < 0.05$).[†]Mann-Whitney test.

Source: Authors.

Table 2. Baseline characteristics of patients presenting with reportable preventable and non-preventable events, in processes represented by FEPASDE (S.C.A.R.E.) Colombia 1999 to 2014.

Variable	Exposure		P
	Preventable RE n=268, n (%)	Non-preventable RE n=54, n (%)	
Type of institution (private)	167 (62.3)	32 (59.3)	0.648
Location			
Large	118 (44.0)	21 (38.9)	0.012*
Intermediate	128 (47.8)	21 (38.9)	
Rural	21 (7.8)	12 (22.2)	
Obstetrician gender (male)	206 (76.9)	41 (75.9)	0.861
Type of admission (emergency)	228 (85.1)	45 (83.3)	0.679
Type of process			
Criminal	90 (33.6)	20 (37.0)	0.336
Civil	33 (12.3)	4 (7.4)	
Ethical	112 (41.8)	27 (50.0)	
Administrative	33 (12.3)	3 (5.6)	
Associated processes (yes)	24 (9.0)	5 (9.3)	1.000
Affiliation (contributory)	164 (61.2)	31 (57.4)	0.523
Mode of delivery (C-section)	150 (56.0)	14 (26.0)	0.110
Newborn weight, g [†]	3090 (2650–3600)	3200 (2350–3500)	0.850
Age of patient, y [†]	28 (24–33)	26 (21–31)	0.037*
Gestational age, wk [†]	38.0 (35.0–40.0)	35.5 (15.0–39.0)	0.001*
Age of physician, y [†]	41 (36–47)	43 (37–49)	0.251

RE=reportable event.

Source: Authors.

*Statistical significance ($P < 0.05$).[†]Mann-Whitney test.

event and an unfavorable legal or ethical decision was evaluated in the bi-varied analysis through crude Odds Ratio (OR) and its corresponding 95% confidence interval (CI). Finally, to assess the association between reportable preventable event and an unfavorable legal or ethical decision, adjusted for other variables, a multivariate analysis was conducted using a non-conditional logistic regression model that included the use of a propensity score, which strengthens the validity of the study by providing even more robust estimates, allowing for the

control of unknown confounding variables, considering that this is an observational study with an important risk of confounding bias.^{21,22} The propensity score was estimated for each one of the malpractice claims, including the following covariables: the type of institution, type of admission, type of lawsuit, diagnosis of the fetus, whether the event was associated with the surgical procedure, the age of the patient, and whether the doctor had a history of additional claims given that these variable were considered relevant from the clinical point of view.

These same variables were included in the logistic regression model, together with the weights of the propensity score. Since the 2 groups (cases and controls) were not matched based on the propensity score result, a non-conditional logistic regression model was used. The backward strategy was implemented for the selection of the variables in the final model. In every case a p value of less than 0.05 was considered statistically significant. The analyses were conducted using Stata 13 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

Ethical considerations

The study was evaluated by the Ethics Committee of S.C.A.R.E with minutes' number CE 201509 dated September 1, 2016. The confidentiality and privacy of the obstetricians, the institutions, the patients and persons involved in the process was insured. Being a retrospective study, informed consents were not required.

Results

A total of 64 cases and 258 controls were included. Reportable preventable events were identified in 268 of the 322 lawsuits included (83.2%). When comparing the cases against the controls, the former had a significantly higher frequency of: reportable preventable event, private institution, contributory regimen, civil lawsuits and fetal demise. (Table 1).

When comparing the groups of patients with a reportable preventable event versus patients with reportable non-preventable events or without RE, there were differences in terms of rural located institution, and pre-term gestational age. No differences were found in terms of the other characteristics between the 2 groups (Table 2).

In terms of health care-associated deficiencies, all except for those associated with the administration of medications, were related to the reportable preventable event (Table 3) and failures in prevention and medication treatment were associated with an unfavorable legal or ethical decision (Table 4). The most frequent health care-associated failures were treatment delays (52%) or diagnostic delays (55%); and in terms of system deficiencies, the most frequent were delays associated with the management plan and communication issues (Table 5).

The bivariate analysis to assess the association between preventable RE and the unfavorable legal or ethical decision showed a crude OR of 3.6 (95% CI: 1.3–10.4). Other factors associated with an unfavorable legal or ethical decision were being affiliated to the contributory regimen OR: 2.22 (95% CI 122–419) and management in a private institution. The multivariate analysis including 92% of the data contained in the propensity score model resulted in an OR of 4.42 (95% CI: 2.23–8.76)

Table 3. Association between care deficiencies and the occurrence of a reportable preventable event in processes represented by FEPASDE (S.C.A.R.E.) Colombia 1999 to 2014.

Variable	Exposure		P
	Preventable RE n=268	Non-preventable RE n=54	
Poor performance (yes)	265	34	0.000*
Prevention (yes)	179	4	0.000*
Diagnosis (yes)	226	10	0.000*
Treatment with medications (yes)	21	1	0.490
Systems (yes)	252	21	0.000*

RE=reportable event.

*Statistical significance ($P < 0.05$)

Source: Authors.

between the preventable RE and an unfavorable decision about the process. An important association was also identified between an unfavorable ruling and care delivered at a private institution, with civil, ethical, or administrative processes, a final diagnosis of fetal demise, and obstetrician with a history of additional claims (Table 6). Since health care-associated failures are highly aligned with the occurrence of preventable REs (exposure to be assessed), these were not included in the final model. The goodness of fit of the logistic model was assessed using the Hosmer-Lemeshow test, indicating a good adjustment ($P = 0.32$).

Table 4. Association between deficient care and unfavorable ruling in processes represented by FEPASDE (S.C.A.R.E.) Colombia 1999 to 2014.

Variable	Process result n (%)		P
	Cases n=64	Controls n=258	
Poor performance (yes)	62 (96.9)	237 (91.9)	0.275
Prevention (yes)	37 (57.8)	146 (56.6)	0.016*
Diagnosis (yes)	49 (76.6)	187 (72.5)	0.852
Treatment with medications (yes)	11 (17.2)	11 (4.3)	0.001*
Systems (yes)	60 (93.8)	213 (82.6)	0.057

*Statistical significance ($P < 0.05$)

Source: Authors.

Table 5. Care deficiencies identified in processes represented by FEPASDE (S.C.A.R.E.) Colombia 1999 to 2014.

Service deficiency	Cases n=64, n (%)	Controls n=258, n (%)
Performance		
Avoidable treatment delay	29 (45.3)	106 (41.1)
Inadequate preparation before the procedure	12 (18.7)	45 (17.4)
Technical error	14 (21.8)	39 (15.2)
Prevention		
Avoidable delay in preventive treatment	31 (48.4)	126 (48.8)
Precautionary measures to prevent accidental injury	20 (31.3)	41 (15.9)
Actions in response to test results or findings	9 (14.1)	28 (10.9)
Diagnosis		
Avoidable diagnosis delay	33 (51.6)	132 (51.2)
Response to findings or test results	16 (25.0)	49 (19.0)
Use of the appropriate tests	1 (1.6)	7 (2.7)
Treatment		
Error in the dose or use method	5 (7.8)	7 (2.7)
Use of inadequate or contraindicated medication	2 (3.1)	4 (1.6)
Inadequate treatment follow-up	3 (4.7)	0 (0)
Avoidable treatment delay	1 (1.6)	1 (0.4)
Systems and other		
Delays in prevention or care plan	45 (70.3)	159 (61.6)
Inadequate reporting or communications	2 (3.1)	26 (10.0)
Inadequate monitoring system	4 (6.3)	14 (5.4)
Inadequate hospital service delivery	2 (3.1)	8 (3.1)

Source: Authors.

Discussion

The results of this study indicate that the occurrence of a preventable RE is an independent risk factor for unfavorable legal or ethical decisions in obstetric malpractice claims in Colombia. Other factors associated with unfavorable decisions is the type of process (civil, ethical, or administrative), health care delivered at a private institution, fetal demise, and obstetrician with a history of additional claims by other patients.

With regard to the presence of RE's in malpractice claims, the results of the study are similar to those reported by Studdert et al²³, who describe errors in the delivery of care in 72% of the claims leading to economic compensation in all specialties. This number is higher than the reported by Bishop et al,²⁴ with 47% of AE's in malpractice claims in inpatients, both studies from the United States.

The association between preventable RE and unfavorable litigation rulings has been reported by Phillips et al²⁵. They found in a study on malpractice claims in primary

Table 6. Raw and adjusted OR estimate using logistic regression for the association between the occurrence of a preventable and non-preventable reportable event and favorable and unfavorable decisions in processes represented by FEPASDE (S.C.A.R.E.) Colombia 1999 to 2014.

Covariables	Crude OR	95% CI	Adjusted OR	95% CI
Preventable reportable event	3.6	1.3–10.4	4.4	2.22–8.75
Institution				
Public	1.0		1.0	
Private	1.9	1.05–3.54	2.26	1.13–4.50
Type of process				
Criminal	1.0		1.0	
Civil	8.48	4.07–17.67	14.08	5.50–36.03
Ethical	0.74	0.42–1.30	3.450	1.53–7.98
Administrative	1.17	0.50–2.71	4.80	1.55–14.89
Fetal demise	2.2	1.21–3.82	3.12	1.64–5.94
History of processes	1.97	0.84–4.50	2.27	1.27–4.06

CI=confidence interval, OR=Odds ratio.

Source: Authors.

care, an association between the occurrence of preventable REs and economic compensation. In obstetrics, Pettker et al²⁶ conducted a before–after study, reporting that the implementation of a broad strategy to prevent AEs in obstetrics in an institution, achieved a reduction from 30 to 14 claims between 2003 and 2007 as compared against 1998 to 2002; Ransom et al²⁷ in a case (deliveries ended up in legal claims) study and controls (deliveries that did not end up in claims with the same diagnoses as the cases) found that non-compliance with the clinical management protocols was significantly associated with malpractice claims (47% vs 11%) OR: 5.76 (95% CI 3.59, 9.2).

Regarding to fetal or newborn compromise as a risk factor for an unfavorable litigation decision, Kurki²⁸ in 1997 reported in Finland a study on 801 claims nationwide, where 85% of the claims were filed as a result of events happened during labor; the cause that led to higher economic compensation was fetal asphyxia; Hale reports that neonatal injuries are among the primary causes of obstetric claims in the United States²⁹; similar reports have been made by Domingues³⁰ (2014) in Portugal.

With regard to deficiencies in the health care management, the findings are similar to those reported by Morris

et al³¹ in general surgery malpractice claims, where they find diagnostic failures, treatment delays, surveillance issues, as well as by systems failures in communication and patient management plan. Furthermore, Clark evaluated 189 claims against obstetricians in the United States and found that 75% of those that lead to an economic compensation, showed deficiencies in the health care management.³²

Some of the strengths of this study are that both cases and controls belong to the same population; the analytical approach to this phenomenon is an additional contribution to the prevailing descriptive approach in most of the literature on the topic; the use of the propensity score who strengthens the results and reaches additional control of any confounding factors. Furthermore, the use of a validated methodology to assess REs.

Some of the limitations include the retrospective nature of the study that affects the quality of the information and could be a source of measurement and selection biases; the inability to conduct a subgroup analysis per type of litigation under the Colombian legal system. Finally, it should be highlighted that in case of claims with a high probability of an unfavorable result, occasionally the claim is settled before the court hearing in the Colombian system and therefore these situations could not be captured in this study; however, this potential bias leans the association found towards the null hypothesis.

Conclusion

The occurrence of preventable REs is associated with unfavorable legal or ethical decisions in civil, ethical, and administrative malpractice claims in Colombia. The outcome of a fetal demise is also associated with unfavorable rulings. Failures in patient management and in the operation of the hospital care system provide opportunities for intervention in order to reduce the risk of being subject to medical malpractice liability.

Ethical responsibilities

Protection of persons and animals: The authors declare that no experiments in humans or animals were conducted in this research.

Confidentiality of information: The authors declare that they have followed the protocols established in their workplace on the disclosure of patient information.

Right to privacy and informed consent: The authors declare that no patient data are included in this study.

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Disclosures

JE-S is the Editor-in-Chief of the Colombian Journal of Anesthesiology. GJ is the head of the Medical Advisory Area of S.C.A.R.E. LAR is an advisor to S.C.A.R.E. IACC is the Legal Coordinator of S.C.A.R.E. MV is the President of S.C.A.R.E.

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