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Predicting negligence in female sterilization failure using time interval to sterilization failure: analysis of 131 cases

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BACKGROUND: Sterilization failure due to 'tubal non-occlusion' or 'wrong structure sterilization' is considered negligent, whereas 'spontaneous tubal recanalization' or 'fistula formation' is considered non-negligent. We examined whether interval to pregnancy failure was predictive of a negligent rather non-negligent failure mechanism. We aim to test this hypothesis in a selected population series of known mechanisms of sterilization failure and their time interval to failure. METHODS: Analyses of 131 failed sterilizations pooled from UK (NHS Litigation Authority, Medical Protection Society and our hospital), Australia and a qualitative systematic review. RESULTS: We identified 88 negligent and 43 non-negligent sterilization failures. Filshie and ring methods failed earlier than diathermy and Pomeroy methods. Sterilization failure occurred significantly earlier in negligent than non-negligent failure mechanisms [median failure intervals 7.0 versus 12.0 months; Hazard ratio (2.35 95% CI 1.31–4.21)]. Knowing that sterilization failure occurred early, increased the probability that the failure mechanism was likely to be negligent rather than non-negligent. CONCLUSIONS: A short interval to failure is suggestive of a negligent failure mechanism. There is less certainty in the predictive value of longer time intervals on the mechanism of failure due to a paucity of cases. A national register of failed sterilizations that have been systematically investigated is needed to improve our understanding of negligent and non-negligent failure mechanisms.

Keywords: sterilization; tubal; treatment failure; survival analysis; Bayes theorem

Introduction

Female sterilization is one of the commonest procedures performed worldwide. In 1999, around 50 000 female sterilizations were performed in England in the NHS and charitable sectors (RCOG, 2004). The procedure is performed on mainly healthy women at their request. Where resources permit, the preference is to use a laparoscopic technique that occludes tubal patency through tubal application of a mechanical device (e.g. Filshie, Hulka clip or Fallope ring) or electrocautery. Tubal excision and separation and related techniques (e.g. Pomeroy procedure) are preferred if sterilization is performed at Caesarean delivery.

Conception that occurs after sterilization is termed failed sterilization and can occur several years after the procedure. Two large population-wide studies have reported the 10-year cumulative probability of pregnancy of 18.5 per 1000 procedures (US CREST study; Peterson *et al.* 1996) and 8 per 1000 procedures (Canada; Trussell *et al*., 2003; Table 1). Differences in sterilization failure rates arise due to variation in: the characteristics of the women undergoing sterilization; operator experience; operating centre; sterilization method chosen, and the time interval to resuming sexual activity, post-sterilization and its frequency. However, neither of these studies reported on the precise mechanism of sterilization failure. In the UK, the RCOG (2004) recommends laparoscopic sterilization by either Filshie clip or ring. The 10-year sterilization failure rate for Filshie clip has been reported by studies as 2–3 per 1000 procedures (Table 1).

The psychological and physical morbidity following failed sterilization often leads to litigation (Varma and Gupta, 2004). Women who have undergone sterilization performed negligently are entitled to recover damages according to wrongful conception, negligence and wrongful birth. Also, women are entitled to recover general damages for pain and suffering during pregnancy and delivery, and loss of earnings during pregnancy. A recent judgement in the Australian High Court (Cattanach v Melchior HCA 38, 2003) led the Australian government to amend the Civil Liberty Act to restrict the amount of damages that could be awarded in such situations.

Despite intense medico-legal activity, research into the prevention and causation of sterilization failure is lacking. The mechanism of failure should be identified through a systematic assessment of Fallopian tube histology, X-ray hysterosalpingography and direct pelvic visual inspection. If the mechanism of failure is due to 'tubal non-occlusion' or 'wrong structure sterilization', these are considered negligent mechanisms,

Table 1: Filshie clip failure rates

Study	Period data were collected	Sterilizations performed	Sterilization method	Outcome	Type of study
Peterson *et al*. (1996)	1978–1986	10 685	Various methods	Overall 18.5 per 1000 over 10 years	Prospective cohort multicentre
			Hulka spring clip (1595)	Hulka 36.5 per 1000	
			Silicone rubber band (3329)	Silicone rubber band 17.7 per 1000	
Trussell *et al*. (2003)	1980–1999	311,960	Mainly laparoscopic Filshie clip	8 per 1000 (2496 failures)	Retrospective multicentre
Kovacs and Krins (2002)	1994–1998	30 000 (estimate)	All Filshie	2.4 per 1000 (73 failures)[a]	Retrospective multicentre
Filshie *et al*. (1998)	1982–1992	First 202 responders from a series of 434	All Filshie	2.3 per 1000 (1 failure at 6 months)	Case series
Birdsall *et al*. (1994)	1988–1989	1094	Mainly laparoscopic Filshie clip	12 per 1000 at 12 months[b]	Case series
Sokal *et al*. (2000)	1984–1990	2746	Filshie clips versus rings (2 in each group became pregnant)	1.7 per 1000 for both ring and Filshie clip groups at 12 months	RCT
Dominik *et al*. (2000)	1984–1990	2126	Filshie clips versus Hulka clips (11 pregnancies occurred: 9 Hulka, 2 Filshie)	At 12 months 1.1 per 1000 for Filshie clip. 6.9 per 1000 for Hulka clip group. At 24 months, 9.7 per 1000 for Filshie and 28.1 per 1000 for Hulka	RCT

[a]Kovacs: of the 73 failures, 14 cases were due to operator error, 29 were properly applied clips and 30 cases had unknown reason for failure; [b]Birdsall: registrars had a 1.3% failure rate, consultants 1.9% and when both a consultant and registrar performed the procedure a failure rate was 0.7%. Eighty-six percent (6/7) of failed sterilizations were due to operator error (wrong structure, initial non-occlusion).

whereas 'spontaneous tubal recanalization' or 'fistula formation' mechanisms of failure are considered non-negligent. However, in the majority of failed sterilization cases, even those in the advanced stages of litigation, the mechanism of failure remains unknown as there is no uniform requirement for such cases to undergo systematic enquiry or to be reported to any supervisory national registry. The RCOG (2004) should consider this requirement at the time of the sterilization guideline review in 2006.

Thus, a common scenario in the legal setting is to cast judgement on the likelihood of negligence or non-negligence in cases with unknown mechanism of sterilization failure. Our qualitative systematic review (Varma and Gupta, 2004) pooled 81 cases of sterilization failure that had documented both interval to pregnancy and mechanism of failure. We showed that a greater proportion of early (within 12 months from operation) than late (after 12 months from operation) sterilization failures occurred by a negligent mechanism. We, therefore propose that interval to sterilization failure may represent a surrogate marker of negligence and non-negligence. Our aim was to (i) determine if sterilization failure occurred earlier in negligent than non-negligent groups and (ii) determine if time interval to sterilization failure was predictive of negligence.

We aim to test this hypothesis in a selected population series of known mechanisms of sterilization failure and their time interval to failure.

Materials and Methods

A written application was made to NHS Litigation Authority (NHSLA), Medical Defence Union (MDU) and Medical Protection Society (MPS) requesting anonymized information on failed sterilization cases. The NHSLA provided 16 cases and the MPS provided 8 cases. Similar anonymized failed sterilization cases that had been subject to litigation proceedings were retrieved from our hospital legal services department ($n = 12$) and a series from an Australian population ($n = 14$) (Femcare, 2004). These cases were pooled with those identified in our previously published qualitative systematic review (Varma and Gupta, 2004) ($n = 81$). A total of 131 failed sterilization cases were identified that reported mechanism of sterilization failure, interval to pregnancy and method used for each case. We have only included cases where the cause of sterilization failure has been established either by direct pelvic visualization or histology of the Fallopian tubes or a combination of both. Most of our data series examines Filshie clip sterilization failures as our data set emanates from countries where Filshie clip predominates as the preferred sterilization method (i.e. UK and Australia). The derivation of this set is shown in Table 2.

Statistical analysis

Statistical analysis was undertaken using SPSS version 13. Geometric means were derived by exponentiating the means from the logarithm transformed interval to pregnancy data. Categorical correlations were assessed by chi-squared analysis. Time-to-event methods (Kaplan–Meier and Cox regression) were used to investigate covariates impacting on time interval to pregnancy. Graphs of log cumulative hazard for failure against time interval for negligent and non-negligent cases were found to be parallel indicating that the proportional hazards assumption did not appear to be violated thereby enabling the valid use of the Cox proportional Hazard regression model. The probability that a randomly selected case was negligent given sterilization failure before a specified time interval was calculated using Bayes' theorem.

Results

Overall interval to pregnancy

The mean age for the group was 33.2 years (SD 4.4; 95% CI 31.9–34.4; range 24–42 years). The arithmetic mean interval

Table 2: Databases used to acquire failed sterilization records

Source of cases	NHSLA	MPS	BWH	Australian series	Qualitative systematic review	Used in study
Dates of sterilization procedure	1995–2004	1990–2004	1987–1996	1990–2000	1966–2005	
Filshie	70[b]	6	13	31[b]	17	62+ (2)
Diathermy	0	4	0	0	20	24
Ring	1	0	0	0	24	24
Hulka[b]	0	1	0	0	1	(2)
Pomeroy	0	0	0	0	19	19
Total included in study[a]	16	8	12	14	81	131

[a]Only cases that included all three components (mechanism of failure, interval to pregnancy and sterilization method used) were included in the study's analysis; [b]individual separate analysis of two Hulka clip cases would be extremely limited, therefore these were included with the Filshie clip category as both methods utilize similar mechanical tubal occlusive devices. Australian series. This was published in our qualitative systematic review (Varma and Gupta, 2004). BWH, Birmingham Women's Hospital; MPS, Medical Protection Society, UK; NHSLA, National Health Service Litigation Authority.

to pregnancy was 13.0 months (SD 14.2; 95% CI 10.6–15.5; range 1–102 months). The greatest proportion of sterilization failures occurred within 12 months (72.5%).

Negligent and non-negligent failure group compositions and intervals to pregnancy

The distribution in our case series was normalized by natural log transformation of the interval to pregnancy times to give a geometric mean interval to pregnancy of 9.3 months (SD 2.2; 95% CI 8.1–10.6). Unlike the arithmetic mean, the geometric mean is not overly influenced by the large values in a skewed distribution, and so gives a better representation of the average for the purposes of this study.

The frequency distribution for both negligent and non-negligent sterilization failure approximates to a normal distribution (Kolmogorov–Smirnov test of normality: non-negligent, $P = 0.037$; negligent $P = 0.001$) and is depicted in Fig. 1. Negligent and non-negligent failures were shown to be statistically significantly different populations groups with differing frequency distributions [Mann–Whitney ($P < 0.001$); Kolmogorov–Smirnov ($Z = 2.851$; $P < 0.001$)].

Kaplan–Meier survival analysis showed that negligent failures occur significantly earlier than non-negligent failures (Log rank $P = 0.001$); the mean intervals for negligent and non-negligent failure were 7.5 and 14.2 months, respectively (Table 3). Filshie and ring sterilization methods failed

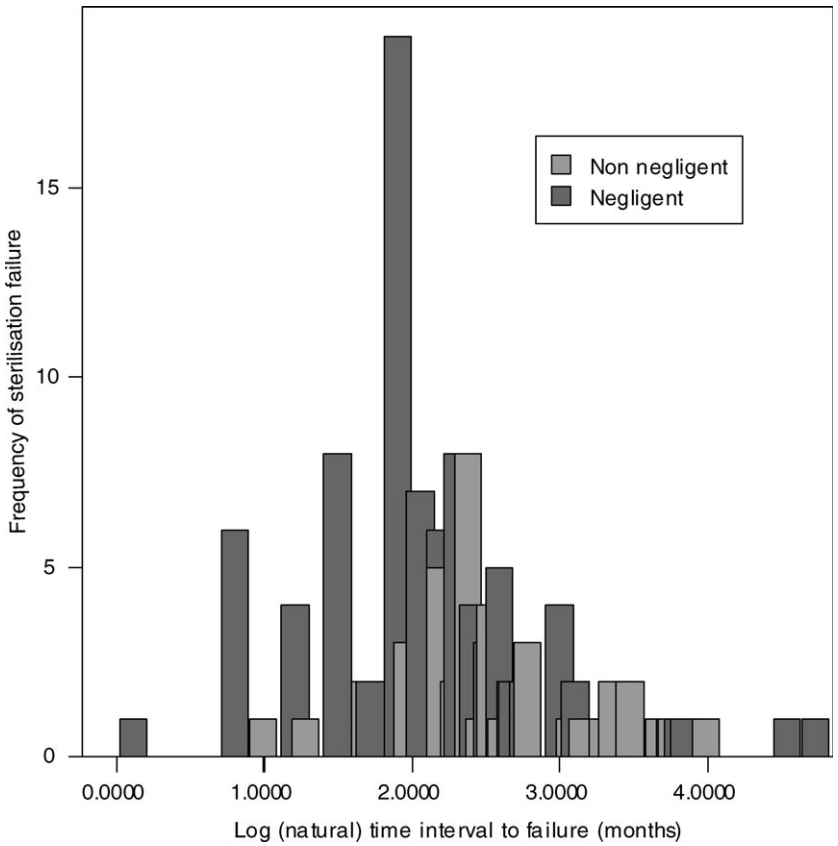

Figure 1: Frequency and time intervals to sterilization failure in negligent and non-negligent groups

Table 3: Negligent and non-negligent failure group compositions and intervals to pregnancy

Mechanism of failure	Negligent	Non-negligent	*P*-value
Number in group	88	43	
Mean interval to pregnancy and 95% CI	7.5 (6.4–8.8)	14.2 (11.8–17.2)	[a,c]Approximately<0.001
Median interval to pregnancy and 95% CI	7.0 (6.1–8.0)	12.0 (10.6–13.5)	
Composition by method of sterilization			
Number of cases/(%)	Filshie 62 (71%) Diathermy 13 (15%) Ring 13 (15%) Pomeroy 0 (0%)	Filshie 2 (5%) Diathermy 11 (26%) Ring (26%) Pomeroy 19 (44%)	[b]<0.001
Composition by mechanism of failure			
Mechanism	Non-occlusion 45 (51%)	Fistula 19 (44%)	[a]<0.001
Mean interval to pregnancy and 95% CI	6.4 (5.2–7.9)	17.1 (12.1–24.1)	
Mechanism	Wrong structure 43 (49%)	Recanalization 24 (56%)	
Mean interval to pregnancy and 95% CI	8.9 (6.9–11.3)	12.4 (10.2–14.9)	

[a]Kaplan–Meier log rank (Mantel-Cox) test for interval to pregnancy difference; [b]Pearson chi-square for category composition difference; [c]Student's *t*-test for equality of means.

significantly earlier than diathermy and Pomeroy methods (Log rank $P = 0.037$); the mean and range intervals to pregnancy are shown in Table 4.

There is a significant association between sterilization method used and negligent and non-negligent mechanism of sterilization failure (chi-square, $P = 0.001$). The Filshie clip, most often failing due to non-occlusion or wrong structure, is the predominant method in negligent failures (71% of cases; Tables 3 and 4). Whereas, Pomeroy, only failing by recanalization and fistula, is the predominant method in non-negligent failures (44% of cases; Tables 3 and 4).

Cox regression analysis of interval to failure

Given that the interval to sterilization failure was associated with sterilization method and mechanism of failure, and that both of these latter variables may interact with each other, a Cox regression analysis was performed. The regression showed that negligence compared with non-negligence significantly increased the hazard potential for sterilization failure, and that negligence ($P = 0.004$) was the only statistically significant covariate when adjusting for sterilization method ($P = 0.237$). Patient age was not a statistically significant factor in the adjusted regression model. The unadjusted hazard ratio for negligence was 1.91 (95% CI 1.31–2.77) and adjusted hazard ratio was 2.35 (95% CI 1.31–4.21). Therefore, interval to pregnancy was predictive of a negligent compared with a non-negligent failure mechanism, irrespective of the sterilization method used. Specifically, the earlier the time interval to failure the greater the likelihood of negligence than non-negligence. This is graphically illustrated in Fig. 2.

Probability of negligence for any case given the interval to pregnancy

The pre-test probability (prevalence) of negligence from our case series is 0.67 (88/131). Thus, the probability of a randomly selected case of sterilization failure being negligent from our case series is 0.67. However, if we assume that time interval of failure may influence the likelihood that the randomly selected case has a negligent failure mechanism, then time interval when sterilization failure occurs may be used as a 'test' that increases or decreases this pre-test probability of negligence.

In Table 5, we have assumed that sterilization failure occurring within a specified time interval (T) to act as a 'diagnostic test of negligence'. We have depicted the post-test probabilities that a randomly selected case from our case series is likely to have a negligent failure mechanism at various time intervals (T) and the corresponding likelihood ratios (LR test positive) of negligence using these intervals as 'diagnostic tests of negligence'. Failure at or before 6 or 9 month intervals appears to

Table 4: Sterilization method and time interval to pregnancy

Method of sterilization	Filshie	Diathermy	Ring	Pomeroy or related surgical method	Overall all Groups	*P*-value
Number in group	64	24	24	19	131	
Interval to pregnancy (months)						
Geometric mean	7.6	11.9	8.2	14.2	9.3	[a]0.037
95% confidence interval	6.1–9.5	8.5–16.6	7.6–9.9	11.4–17.9	8.1–10.6	
Range of time intervals to pregnancy (months) for each method						
Negligent						
Non-occlusion	2–38	3–10	4–5	No cases		
Wrong structure	1–102	9[b]	7–20	No cases		
Non-negligent						
Fistula	14[b]	3–44	6–10	10–48		
Recanalization	10[b]	60[b]	6–13	4–18		

[a]Kaplan–Meier log rank (Mantel-Cox) test for interval to pregnancy difference; [b]single case only, therefore no range.

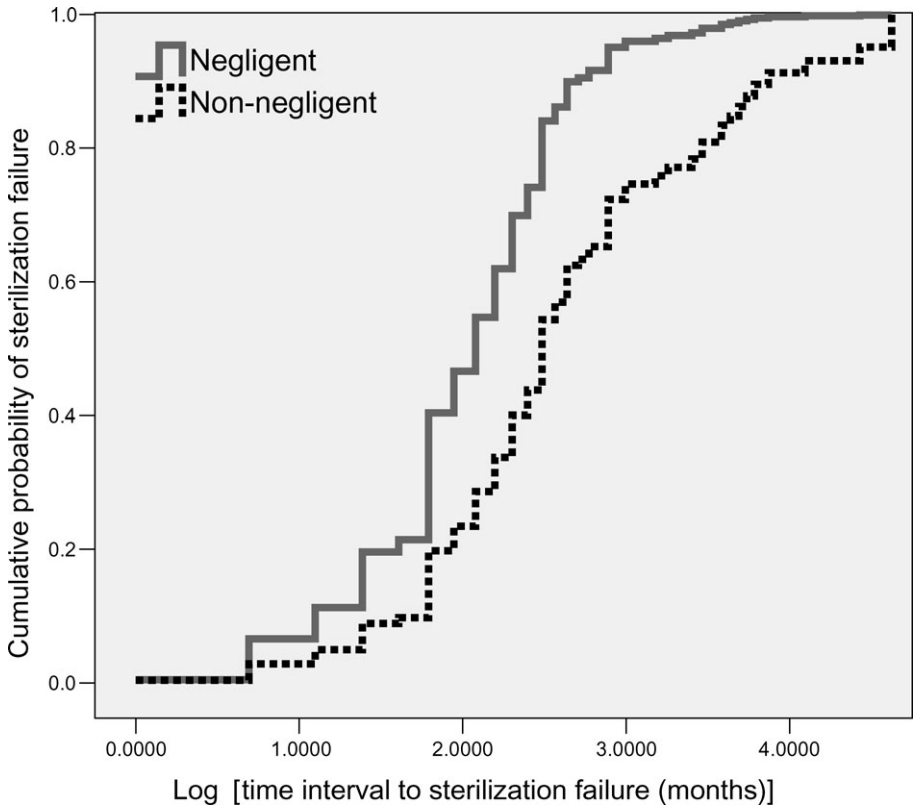

Figure 2: The probability of sterilization failure for negligent and non-negligent cases against time interval to failure (Cox regression model). The graph depicts the 1-minus survival function plot of the adjusted Cox regression model function, i.e. incorporates both sterilization method and failure mechanism covariates. All cases have ultimately failed, therefore for both negligent and non-negligent cases the cumulatively probability is 1 at the maximum recorded time interval for each group. The hazard ratio corresponds to the odds that a case in the negligent group fails before a case in the non-negligent group. Thus, there is a 70% probability [converting Hazard odds of 2.35 to probability by $2.35/(1 + 2.35)$] that sterilization failure will occur earlier in a negligent case than a non-negligent case, irrespective of the sterilization method used. Furthermore, comparing median times (Table 3), negligence reduces the time interval to failure by approximately 5 months (or 42%) compared to non-negligence

provide statistically significant test positive LRs (4.89 and 4.26, respectively). Later failures appear to have lower test positive LRs and are less likely to be predictive of the failure mechanism. However, there is a paucity of late failures available for analysis which may make LRs derived from this group less reliable. Furthermore, we have specified test positive LRs for 9–18 months and 18–84 months intervals, although these are likely to be biased. This is because these intervals and LRs would not factor in the negligent/non-negligent cases that occur either side of the specified time interval.

Table 5: Using time interval of failure as a 'diagnostic test' to predict likelihood of negligent sterilization failure

T[a]	Negligent cases ($n = 88$)	Non-negligent cases ($n = 43$)	Probability[b]	LR test positive[c]
Entire case series of this publication	88	43	0.67	1.00 (0.96–1.11)
Cumulative time intervals from common sterilization completion point				
$0 \leq 6$	40	4	0.91	4.89 (2.03–12.65)
$0 \leq 9$	61	7	0.90	4.26 (2.27–8.64)
$0 \leq 12$	73	22	0.77	1.62 (1.24–2.28)
$0 \leq 18$	81	33	0.71	1.20 (1.03–1.49)
$0 \leq 24$	83	34	0.71	1.19 (1.04–1.46)
$0 \leq 48$	86	42	0.67	1.00 (0.94–1.11)
Consecutive time intervals after sterilization completion				
>0 and ≤ 9	61	7	0.90	4.26 (2.27–8.64)
>9 and ≤ 18	20	26	0.44	0.38 (0.24–0.59)
>18 and ≤ 84	6	10	0.38	0.29 (0.12–0.73)

[a]Time interval that sterilization failure has occurred within (months); [b]probability that randomly selected case is negligent from the study series given failure time interval T (corresponds to predictive value of positive test); [c]likelihood ratio (LR) of negligence given failure occurred within the time interval T.

Ordinarily, the probability that a randomly selected case is negligent could be calculated by knowing the pre-test odds and negligence test positive LR for that time interval and the Bayesian equation:

$$\text{Pre-test odds} \times \text{Likelihood ratio for that time interval} = \text{Post test odds}$$

$$\text{Odds} = \frac{\text{Prob.}}{1 - \text{Prob.}} \quad \text{Prob.} = \frac{\text{Odds}}{1 + \text{Odds}}$$

Let us suppose that a sterilization failure occurred at 9 months and we use the test of negligence as the time interval $0 \leq 9$ months (LR test positive 4.26).

In our case series, the pre-test probability that a randomly selected case is negligent increases from 0.67 to 0.90 (pre-test odds of $2.03 \times 4.26 = 8.65$ post-test odds; post-test probability is $8.65/1 + 8.65 = 0.90$) knowing that if it had failed at 9 months.

However, our case series is highly selected. Let us assume a pre-test probability of negligence of 0.5 ($\text{Odds} = 0.5/1 - 0.5 = 1$), which would correspond to that used in legal proceedings in cases with unknown mechanism of sterilization failure. In this situation, the pre-test probability that a randomly selected case is negligent increases from 0.50 to 0.81 (pre-test odds of $1 \times 4.26 = 4.26$ post-test odds; post-test probability is $4.26/1 + 4.26 = 0.81$) knowing that it had failed at 9 months.

Discussion

Analysis of our selected series of failed sterilizations has shown that a short interval to failure is suggestive of a negligent failure mechanism. There is less certainty in the predictive value of longer time intervals on the mechanism of failure. Negligence compared with non-negligence reduces the interval to failure by 5 months (based on median interval comparisons). There is limited evidence from our highly selected case series that LRs for tests of negligence may be helpful in predicting whether a randomly selected case is negligent. However, this only appears to be of value for cases with early sterilization failure (below 9 months) and this concept requires validation in larger appropriately designed studies. Nonetheless, such a test may have important medico-legal ramifications in cases with unknown mechanism of failure.

Our case series represents the world's largest number of failed female sterilizations with concurrent knowledge of their mechanism of sterilization failure and interval to pregnancy. Until this study, issues involving mechanism of failure, had not been addressed by the two largest studies of sterilization failure (Peterson *et al.*, 1996; Trussell *et al.*, 2003) or the cochrane review (Nardin *et al.*, 2007). We had predicted this hypothesis in our earlier qualitative systematic review (Varma and Gupta, 2004). Like previous studies, we showed differences in time interval to sterilization failure for different sterilization methods (Peterson *et al.*, 1996), however, we found no significant effect of age on tendency to sterilization failure that had been reported by a previous study (Trussell *et al.*, 2003).

We agree there may be caveats when interpreting our results, particularly as our data series is highly selective. First, our data series is composed of cases from 1975 onwards. Advances in training in laparoscopic procedures and laparoscopic video imaging may be underrepresented in our data series leading us to overestimate the proportion of negligence (operator-fault) that may occur with earlier (1970–1990s) sterilization failures. Secondly, our study sample is not derived from a repository of systematically investigated and recorded sterilization failures. Thirdly, although NHSLA has systematically collected data on litigated cases in England since 1995, there are many exclusion criteria allowing hospitals to locally manage some failed sterilization cases thereby limiting case ascertainment. We were unable to examine the individual records from the NHSLA and MPS databases to verify the accuracy of the failure mechanism reported. Consequently, we are uncertain whether there are inconsistencies in the classification of failure mechanism used. Finally, we anticipate a general under-reporting of non-negligent sterilization failures in the published literature and in the legal databases that we used for the study. Therefore, it is likely that our overall estimate of the prevalence of negligence (i.e. pre-test probability of 0.67, $88/88 + 43$) from our case series is likely to exceed the upper limit of prevalence that would be obtained from the true population of systematically acquired sterilization failures.

Negligence litigation in the UK is based on the claimant producing the burden of proof (prove negligent action has occurred) and the standard of proof is the civil standard (balance of probabilities). The claimant has to show that the harm suffered (i.e. failed sterilization) on the balance of probabilities, is more likely than not to be caused by a negligent action than non-negligent action. In this legal situation, an unknown mechanism of sterilization failure could be presumed to have a pre-test robability of negligence of 0.5 (legal equivalence). If a case had failed at say 9 months, then applying our test of failure before or at 9 months would provide a post-test probability of negligence of 0.81 which may be interpreted by legal experts as highly suggestive of a negligent failure mechanism. Nonetheless, we would always endorse that the actual negligent or non-negligent cause of sterilization failure can only be established after a systematic clinical, histopathological and X-ray examination process. Furthermore, this concept of predicting negligence using time intervals would need to be validated in a larger population base of systematically investigated sterilization failures.

A national register of systematically collected and investigated failed sterilizations, as recommended by the RCOG (2004), would quantify the exact prevalence (pre-test probability) of negligent and non-negligent failure mechanisms, and would advance research into this area. Little is known on non-negligent failure mechanisms due to poor case ascertainment, but such a registry may even show that the probability of a non-negligent sterilization failure equated to the probability of a negligent sterilization failure for a particular sterilization method, which would then make any legal claim for negligent sterilization unlikely to succeed. Furthermore, such a registry could identify areas of substandard care that could be used as an impetus to improve medical training and design effective clinical risk prevention strategies.

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