Ismail S¹, Nicholson S²

1. Singleton Hospital, Swansea, Wales, UK, 2. National Health Service Litigation Authority, London, England, UK

ANALYSIS OF UROGYNAECOLOGICAL LITIGATION IN ENGLAND OVER 14 YEAR PERIOD.

<u>Hypothesis / aims of study</u> Litigation represents a serious drain on healthcare resources (1) and a painful worry for healthcare staff (2). However, analysis of medico-legal cases is an informative feedback to avoid litigation (3). To date, no such analysis has been carried out in relation to urogynaecology. All medico-legal cases in England are registered with the National Health Service Litigation Authority (NHSLA) at the investigation stage, before a claim is actually made.

The aim of this study was to establish the nature and pattern of urogynaecological litigation, as registered on the National Health Service Litigation Authority (NHSLA) database.

Study design, materials and methods The National Health Service Litigation Authority (NHSLA) database was searched for urogynaecology-related registered cases from its inception in 1995/1996 till 2008/2009. Search was made in relation to continence and pelvic organ prolapse surgery, obstetric anal sphincter injuries as well as urogynaecological problems related to obstetrics and gynaecology, both surgical and non surgical.

Results A total of 633 urogynaecology-related cases were registered between 1995/1996 till 2008/2009. An annual distribution of these cases according to their status at the time of data collection (April 2009) is shown in table 1. Six cases (0.9%) were incidents which were investigated but no claims were made. Background features of cases are shown in table 2. Detail of payments made for cases is shown in table 3.

Year of incidence	Total No.	No. of incidents	No. of claims	No. of open claims	No. of closed claims
1995/96	47	0 (0%)	47 (100%)	0 (0%)	47 (100%)
1996/97	36	0 (0%)	36 (100%)	15 (41.7%)	21 (58.3%)
1997/98	36	0 (0%)	36 (100%)	0 (0%)	36 (100%)
1998/99	51	0 (0%)	51 (100%)	0 (0%)	51 (100%)
1999/00	54	0 (0%)	54 (100%)	0 (0%)	54 (100%)
2000/01	52	1 (2%)	51 (98.1%)	6 (11.5 %%)	45 (86.5%)
2001/02	52	1 (2%)	51 (98.1%)	28 (53.8%)	23 (44.2%)
2002/03	69	3 (4.3%)	66 (95.7%)	20 (29%)	46 (66.7%)
2003/04	59	0 (0%)	59 (100%)	1 (1.7%)	58 (98.3%)
2004/05	68	1 (1.5%)	67 (98.5%)	15 (22.1%)	52 (76.5%)
2005/06	62	0 (0%)	62 (100%)	8 (12.9%)	54 (87.1%)
2006/07	32	0 (0%)	32 (100%)	9 (28.1%)	23 (71.9%)
2007/08	10	0 (0%)	10 (100%)	3 (30%)	7 (70%)
2008/09	5	0 (0%)	5 (100%)	4 (80%)	1 (20%)
Total	633	6 (0.9%)	627 (99.1%)	109 (17.2%)	518 (81.8%)

Table 1: Annual distribution of registered cases.

Feature	Statistical test	Result
Annual incidence	Mean <u>+</u> SD	45.2 <u>+</u> 19.5
Time between incidence and notification	Mean + SD	1.8 <u>+</u> 0.6 years
- Obstetrical	Number (%)	387 (61.1%)
= Obstetric anal sphincter injuries		322 (50.9%)
+ Confirmed		310 (49.0%)
+ Suspected		12 (1.9%)
= Bladder damage		14 (2.2%)
= Catheterisation		4 (0.6%)
- Gynaecological		246 (38.9%)
= Urogynaecological surgery		111 (17.5%)
= General gynaecological surgery		105 (6.6%)
Consent issues	Number (%)	18 (2.8%)
Fistula	Number (%)	64 (10.1%)
- Urinary		36 (56.3%)
- Bowel		25 (3.9%)
Missed swab	Number (%)	4 (0.6%)
Ureteric injury	Number (%)	29 (4.6%)
- Obstetric		4 (0.6%)
 Continence operation 		1 (0.2%)
 Prolapse surgery 		1 (0.2%)
- Hysterectomy		20 (3.2%)
- Laparoscopic procedure		4 (0.6%)

Table 2: Background features of registered cases

Type of payment	No. of cases	Minimum	Maximum	Total
Damages	313(60.4%)	£1,750.00	£600,000.00	£17,448,673.33
Defence costs	396 (76.4%)	£18.50	£93,191.17	£4,573,290.35
Claimant costs	309 (59.7%)	£18.50	£239,593.12	£9,341,583.13
Total	415 (80.1%)	£18.50	£653,206.93	£31,363,546.81

Table 3: Payments made for closed cases.

Interpretation of results An average of 50 urogynaecological cases were registered each year in England between 1995/96 and 2008/09. Obstetric anal sphincter injuries (OASIS) were the largest group, followed by continence and prolapsed procedures, general gynaecological as well as general obstetric care. As the data documented in the database are extracted from claims, they suffer from inherent limitations in relation to clinical detail and specification, which limited further analysis and must be borne in mind when looking at the figures. Claims were made for 99% of registered cases and damages as well as claimant costs were paid for 60% of closed cases. Over three quarters of closed costs incurred defence costs. The cost of open cases was not available, so the actual cost to the National Health Service budget is higher than the 31 million pounds Sterling paid for closed cases. In addition, it is likely that there are cases that are yet to be registered with the National Health Service Litigation Authority (NHSLA), given the time delay between incidence and notification. The total number of cases, and thus cost, is certain to be higher. Moreover, there are open cases (109 at the time of data collection), with their ongoing cost. Besides, there is the overhead cost of staff employed to manage these incidents and claims, both locally as well as centrally. Furthermore, dealing with litigation entails time and stress to all involved, and the cost of such aspects can be immeasurable.

<u>Concluding message</u> Obstetric anal sphincter injuries, continence and prolapsed surgery as well as urogynaecological complications of other gynaecological and obstetrical procedures are potential medico-legal areas. This should guide better risk management to avoid litigation with all its drawbacks. More research is needed in this area, which will be helped by more clinically orientated data recording on the National Health Service Litigation Authority (NHSLA) database and establishing similar databases in Wales, Scotland and Northern Ireland.

References

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require ethics committee approval because	None required, as the study is a retrosepctive analysis of medicolegal cases and did not involve any intervention
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	No