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Original Research

A critical review of thyroidectomy consent in the UK

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ABSTRACT

Background: In 2015-16, the National Health Service (NHS) Litigation Authority received 10,965 claims for clinical negligence, with surgery having the highest number of claims. Currently a sum amounting to 25% of the annual NHS budget has been ring-fenced to meet extant claims. Claims made on a basis of inadequate informed consent are increasingly seen with many achieving a successful plaintiff outcome. There are presently no UK guidelines for thyroidectomy consent.

Method: A prospective study was performed to investigate current consent practice among the British Association of Endocrine and Thyroid Surgeons (BAETS) membership and patients having previously undergone thyroidectomy. For surgeons, the Bolam legal test applied where surgeons declared what risks and complications they routinely consented for during their practice. A study was also undertaken in patients who had previously undergone thyroidectomy for cancer applying the rule of Montgomery.

Results: Consent practice from 193 surgeons and data from 415 patients was analysed. In total thyroidectomy for cancer, 95% of surgeons consent for Recurrent Laryngeal Nerve (RLN) injury and temporary or permanent voice change. 70% specifically consent for External Laryngeal Nerve (ELN) injury, 50% for tracheostomy and 55% for general anaesthetic associated complications. Analysis of patient data showed they would like to be consented for far more risks than they are presently informed about in general medical practice. There was significant variation in the consenting practice in BAETS surgeons.

Conclusion: A BAETS approved consensus guideline to standardise UK consent practice would be appropriate. This may reduce complaints, litigation claims and guide expert witnesses.

1. Introduction

The NHS Litigation Authority received 10,965 claims for clinical negligence in 2015–2016, with surgical claims being highest. A sum equivalent to 25% of the annual budget is now ring-fenced to meet existing claims [1]. Successful plaintiff claims based on inadequate informed consent are now increasingly seen.

The UK population has become increasingly litigious with a significant increase in complaints and litigation in medical practice. In thyroidectomy, the commonest reason for successful plaintiff claims are complications and inadequate informed consent [2].

Presently there are no UK national guidelines or consensus for thyroidectomy consent. In 2015, UK consent law underwent a fundamental change moving from the principle of Bolam to Montgomery law [3].

Prior to Montgomery law being introduced, medico-legal claims were subject to the legal test outlined by the principle of Bolam [3]. The Bolam principle relies on the opinion of a body of medical professionals. In order to pass the Bolam test a doctor must have acted/behaved in a way which was deemed acceptable by a body of medical professionals. Until recently we were consenting patients for procedures based on the Bolam principle.

Montgomery case law stipulates that patients should now be consented on the basis of what they may wish to know. All serious and life altering complications should be documented even if rare. A discussion is required about alternative treatments and the doctor must ensure time for patient reflection, a guarantee of both patient capacity and understanding in the shared consent process is also necessary. It is the surgeon's duty to ensure that the patient is aware of any material risks involved in the recommended treatment. Materiality is whether, in the specific circumstances, a reasonable person in the same position as the patient would be likely to attach a significance to the risk. Whether or not a risk is material doesn't only depend on how frequently it occurs and therefore although we are encouraged to quote surgeon specific risks, the emphasis is now on the assessment of material risk for that particular patient [4].

There are presently no UK consent guidelines or consensus for thyroidectomy. This study aimed to review the present consent practice

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among a large cohort of UK thyroid surgeons. It also intended to view Thyroid consent from the perspective of the patient based on the principles outlined by Montgomery law.

2. Materials and methods

Part 1 of the study analysed thyroidectomy consenting practice in 193 UK surgeons. An anonymised questionnaire was sent to all British Associations of Endocrine and Thyroid Surgeons (BAETS) using Qualtrics questionnaire software. Each surgeon selected from a list of complications what they routinely consent patients for when performing total thyroidectomy and hemithyroidectomy (having had no previous surgery) for the management of thyroid cancer.

Part 2 of the study was a national survey looking at consent from a patient perspective. An anonymised questionnaire was distributed through the Butterfly Thyroid Cancer Trust using Qualtrics questionnaire software. A Delphi method (a structured interactive method for a panel of experts to communicate) was used at a focus group to review questionnaire wording prior to circulation.

All patients had previously undergone surgery for treatment of their thyroid cancer. The same list of complications sent to surgeons was used (modified to aid patient understanding and avoid medical jargon). Patients selected complications they considered should be discussed with them prior to giving consent for surgery.

A two-sample *t*-test was performed using SPSS (version 20) to compare surgeon and patient selection of complications and risk.

This work has been reported in line with the Consolidated criteria for Reporting Qualitative Research (COREQ) criteria.

3. Results

The response rate to the survey was 60.7%. 193 surgeon questionnaires were completed by consultant surgeons from a range of surgical disciplines: ENT surgery 50%, endocrine surgery 22%, breast surgery 16%, general surgery 9%, and maxillofacial surgery 2%. 93% of surgeons perform benign and malignant thyroid surgery.

38% of surgeons had performed thyroid surgery for between 10 and 20 years. There was a wide surgeon variation in the number of thyroid operations performed annually (range 1–10 thyroidectomies performed annually to > 101 thyroidectomies performed annually, median 41–50 thyroidectomies performed annually. 17% of surgeons performed between 31 and 40 with 15% having a practice on over 100 thyroidectomies each year.

Tables 1 and 2 show the outcome of the surgical questionnaire. The list of complications and percentage of surgeons selecting each complication they routinely consent for is shown in Table 1.

95% of surgeons consent for 'injury to the recurrent laryngeal nerve and temporary or permanent voice change. 70% specifically consent for external laryngeal nerve injury with voice change. 50% consent for tracheostomy.

The results for hemithyroidectomy are shown in Table 2. 64% of surgeons consent for hypothyroidism and a need for Levothyroxine.

The survey did not request information about surgeons quoting their own complication rate.

The results from 415 completed patient questionnaires were analysed in this study. Table 3 shows the equivalent results for patients. Two-thirds of patients (67.5%) wished to know about all potential risks before consenting for surgery. Table 4 shows the complications and percentage of patients selecting that complication as something they would like to have discussed before giving consent. 50% of patients wished to know about the risk of tracheostomy. Table 5 shows the two sampled *t*-test to assess for significant differences between the patients' and surgeons' selection of risks. For most risks there is a significant difference in what patients would like to know and what surgeons routinely consent for.

Table 1
Risks routinely consented for by surgeons when performing total thyroidectomy.

Risk	Surgeons selecting this as a risk they routinely consent for %
Hypoparathyroidism and the need for calcium ± vitamin D replacement (temporary/permanent)	95.9
Injury to recurrent laryngeal nerve and change in voice (temporary/permanent)	95.3
Bleeding	94.3
Infection	84.5
Injury to the external laryngeal nerve and change in voice (temporary/permanent)	69.9
Hypothyroidism and need for levothyroxine	63.7
Tracheostomy	49.7
Seroma	31.6
Risk of anaesthesia and associated complications	54.4
Injury to major artery	5.69
Horner's syndrome	4.76
Injury to major vein	4.66
Tracheal injury	4.14
Oesophageal injury	2.59
Injury to Vagus	2.07

Table 2
Risks routinely consented for by surgeons when performing hemi-thyroidectomy (No prior thyroid surgery).

Risk	Surgeons selecting this as a risk they routinely consent for %
Injury to recurrent laryngeal nerve and change in voice (temporary/permanent)	93.8
Bleeding	90.2
Infection	82.4
Injury to the external laryngeal nerve and change in voice (temporary/permanent)	67.9
Hypothyroidism and the need for Levothyroxine	63.7
Seroma	30.1
Hypoparathyroidism and the need for calcium ± vitamin D replacement (temporary/permanent)	25.4
Risk of anaesthesia and associated complications	45.6
Tracheostomy	5.18
Injury to major artery	3.63
Injury to major vein	3.11
Tracheal injury	2.59
Horner's syndrome	2.59
Oesophageal injury	1.55
Injury to Vagus	1.04

4. Discussion

This study revealed a large variation in the consent practice of BAETS surgeons, who by selection bias have a dedicated interest in thyroid surgery. Not all surgeons performing thyroidectomy in the UK are either members of the BAETS or engage in the United Kingdom Registry or Endocrine and Thyroid Surgeons (UKRETS) even though this has been mandatory in England since 2013. It might be speculated, therefore, that variation in thyroid surgery consent might be considerably greater than revealed in this study. We also acknowledge that

Table 3
Patients' opinions on consent.

Statement	Patients agreeing with the statement (%)
I would like to know about all potential risks	67.5
I would like to know both the common and dangerous risks	18.7
I would like to know only about the common risks (risks greater then 1:100)	6.45
I would like to know only the dangerous risks	5.53
I would not like to know any of the risks	1.84

Table 4
Risks that patients would like to be routinely consented for by surgeons when undergoing thyroid surgery.

Risk	Patients selecting this as a risk they would like to be consented for when undergoing a total thyroidectomy (or hemithyroidectomy without prior surgery*) %
*Hypothyroidism and the need for Levothyroxine	96.2
Injury to recurrent laryngeal nerve and change in voice (temporary/permanent)	82.9
Hypoparathyroidism and the need for calcium ± vitamin D replacement (temporary/permanent)	76.1
Injury to the external laryngeal nerve and change in voice (temporary/permanent)	71.5
Tracheal injury	66.0
Risk of anaesthesia and associated complications	65.1
Bleeding	59.3
Tracheostomy	55.7
Infection	54.2
Oesophageal injury	51.8
Injury to major artery	50.8
Injury to Vagus	50.8
Injury to major vein	46.7
Horner's syndrome	45.1
Seroma	40.5

Table 5
The differences between the patients' and surgeons' selection of risks and Two sampled *t*-test to assess for significance.

Risk	Surgeons (%)	Patients (%)	Two sample *t*-test
Bleeding	94.3	59.3	$P < 0.0001$
Hypoparathyroidism and the need for calcium ± vitamin D replacement (temporary/permanent)	95.9	76.1	$P < 0.0001$
Infection	84.5	54.2	$P < 0.0001$
Hypothyroidism and need for levothyroxine	63.7	96.2	$P < 0.0001$
Oesophageal injury	2.59	51.8	$P < 0.0001$
Injury to vagus	2.07	50.8	$P < 0.0001$
Injury to major artery	5.69	50.8	$P < 0.0001$
Injury to major vein	4.66	46.7	$P < 0.0001$
Tracheal injury	4.14	66.0	$P < 0.0001$
Injury to recurrent laryngeal nerve and change in voice (temporary/permanent)	95.3	82.9	$P = 0.0005$
Risk of anaesthesia and associated complications	54.4	65.1	$P = 0.0229$
Seroma	31.6	40.5	$P = 0.1758$
Injury to the external laryngeal nerve and change in voice (temporary/permanent)	69.9	71.5	$P = 0.2778$
Tracheostomy	49.7	55.7	$P = 0.9824$

the surgeons replies to the survey may not be an exact reflection of the reality of their practice. It should be noted than an audit of the consent forms did not take place.

The study also shows a clear discrepancy with what the surgical community considers patients should know (Bolam), compared to what patients would like to know (Montgomery). This represents a failure of surgeons to adapt, change and align their consent practice with Montgomery law and is likely to be due to the fact that surgeons are not aware of what patients would like to know. Although, it should be noted that the study took place shortly after the Montgomery law was introduced and the study may not reflect more recent changes in practice. A lack of national guidance and consensus on thyroid surgery consent clearly facilitates such variation. Finally, it leaves surgeons open to legal challenge, complaints and litigation.

Patients in this study are not representative of the population as a whole, as there is clear selection bias. All are members of the Butterfly Thyroid Cancer Trust, having previously had surgery for thyroid cancer. They are therefore likely to be reflecting on their personal experience of the consent process. Nonetheless, the basic tenets and principles remain unchanged. There is clearly a need for a national guidance and consensus on thyroidectomy consent.

Other specialties have adopted procedure specific consent forms (PSCFs). The British Orthopaedic Association has endorsed a website which provides free access to PSCFs for surgeons. Both Kondziolka et al.

I confirm I have had explained to me the purpose and likely benefits of Total Thyroidectomy.

I further confirm that it has been explained to me that the proposed operation may not be fully successful and that there are attendant risks and possible adverse side effects.

I am aware that my anonymised surgical data is submitted into the national registry.

The main ones in terms of seriousness and likelihood being as follows:

Bleeding, Infection, Vocal Cord Palsy and Voice change which may be temporary or permanent, Parathyroid gland injury requiring Vitamin D and Calcium support which may be temporary or permanent, Tracheostomy, Seroma, Scar problems – cosmetic or hypersensitivity.

It has also been explained to me that this list is not exhaustive of all the possible adverse effects and that there remain other extremely remote possibilities. I have been advised that I may have an interview with the doctor in charge of the treatment to discuss these and I confirm either:

(1). I have had such a discussion and wish to proceed. or;-
(2). I am content to proceed without such a discussion.

I further confirm that I am aware that circumstances may arise where I might need further urgent treatment at a time when it is not possible to consult with me to obtain my informed consent. In such circumstances I authorize those carrying out the procedure/treatment to do all that any reasonably competent suitably qualified medical practitioner would consider advisable in such circumstances. I therefore consent and consider it to be in my best interests that the operation goes ahead.

Fig. 1. Outline consent document – total thyroidectomy.

and Finch et al. have shown that patients have better recall of the risks of surgery when they have been consented with a PSCF rather than a conventional consent form [5,6].

Fig. 1 is a suggested format for total thyroidectomy and Fig. 2 for hemithyroidectomy consent. It takes into account Montgomery law in addition to consent to enter patient data into the UKRETS (resulting from the recent change in data protection through the EU General Data Protection Regulation (GDPR) - 25th May 2018).

5. Conclusion

This study revealed a large variation in the consent practice of BAETS surgeons. A lack of national guidance and consensus on thyroid surgery consent clearly facilitates such variation. The study also shows a clear discrepancy with what the surgical community considers patients should know (Bolam), compared to what patients would like to know (Montgomery). There is a need for a national guidance and consensus on thyroidectomy consent. We have suggested a format for total thyroidectomy and for hemithyroidectomy consent.

Provenance and peer review

Not commissioned, externally peer reviewed.

Data statement

Data will be provided upon request. The questionnaire data was exported from Qualtrics secure questionnaire software into SPSS and analysed in SPSS.

I confirm I have had explained to me the purpose and likely benefits of hemithyroidectomy

I further confirm that it has been explained to me that the proposed operation may not be fully successful and that there are attendant risks and possible adverse side effects.

I am aware that my anonymised surgical data is submitted into the national registry.

The main ones in terms of seriousness and likelihood being as follows:

Bleeding, Infection, Vocal Cord Palsy and Voice change which may be temporary or permanent, hypothyroidism, Seroma, Scar problems – cosmetic or hypersensitivity.

It has also been explained to me that this list is not exhaustive of all the possible adverse effects and that there remain other extremely remote possibilities. I have been advised that I may have an interview with the doctor in charge of the treatment to discuss these and I confirm either:

(1). I have had such a discussion and wish to proceed. or;-
(2). I am content to proceed without such a discussion.

I further confirm that I am aware that circumstances may arise where I might need further urgent treatment at a time when it is not possible to consult with me to obtain my informed consent. In such circumstances I authorize those carrying out the procedure/treatment to do all that any reasonably competent suitably qualified medical practitioner would consider advisable in such circumstances. I therefore consent and consider it to be in my best interests that the operation goes ahead.

Fig. 2. Outline consent document for hemithyroidectomy.

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Author contribution

Charlotte McIntyre: Methodology, Software, Data curation, Writing- Original draft preparation, Visualization, Investigation, Validation, Data curation.

Prof Neil Tolley: Conceptualization, Methodology, Visualization, Investigation, Supervision, Validation, Writing- Reviewing and Editing.

Conflicts of interest

No conflicts of interest.

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CRediT authorship contribution statement

C. McIntyre: Methodology, Data curation, Software, Investigation, Validation, Writing - original draft. **N. Tolley:** Conceptualization, Methodology, Data curation, Validation, Writing - review & editing, Supervision.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2019.04.015.

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