Who is at risk of death from Nephrectomy? An analysis of thirty-day mortality following 21,380 nephrectomies in three years of the British Association of Urological Surgeons (BAUS) National Nephrectomy Audit

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Abstract

Objective To ascertain contemporary overall and differential 30-day mortality (TDM) following all types of nephrectomy in the UK and to identify potential new risk factors for death.

Patients and methods Retrospective analysis of 110 deaths within 30 days of surgery out of the total of 21,380 nephrectomies entered, and calculation of odds ratio (OR) and 95% confidence interval (CI) for thirty day mortality (TDM) based on peri-operative characteristics.

Results TDM overall 110/21380 (0.5%). TDM following radical, partial, simple nephrectomy, and nephro-ureterectomy was 0.6% (63/11057), 0.1%(4/3931), 0.4% (11/2819) and 0.9% (28/3091) respectively.

TDM increased with age, stage, blood loss, operative time and performance status. Blood loss 1-2L was associated with a great TDM than blood loss 2-5L (OR 1.38; 95% CI 1.03-2.24). Conversion from minimally invasive surgery is higher risk than those not converted (OR 2.53; 95%CI:1.14-4.51. Curative surgery is safer than cytoreductive surgery (OR 0.31; 95% CI:0.18-0.54). There is an association between surgical volume and TDM.

Limitations include retrospective analysis with no root cause analyses performed.

Conclusions This study provides contemporary insights into the true risks of all types of nephrectomy. The 30-day mortality after nephrectomy in the UK appears acceptably low at 0.5%. Established risk factors have been confirmed and novel risk factors have been identified viz, modest blood loss (1-2L) and conversion.

Introduction

There is increasing focus on the outcomes of surgical procedures and the factors associated with those outcomes [1]. This information is important to surgeons, patients and policy-makers alike. In the UK this was highlighted in 2012 with the issuing of a government directive for specialist surgical associations to publicly report the outcomes of common surgical procedures [2]. The UK government directive was controversial but followed on from the largely successful initiatives in cardiothoracic surgery to openly publish outcomes [3]. The British Association of Urological Surgeons (BAUS) chose thirty-day mortality (TDM) following nephrectomy as the index outcome.

Knowing the risk of death and the reasons for it can be difficult. The literature suggests surgical mortality following nephrectomy varies from 0.6-3.6% with the lowest rates often being reported by large specialist centres [4]. The published literature has well documented limitations: there is a bias towards the publication of success as generally only teams with outstanding results present and publish [5-7]. Furthermore, some clinical scenarios may be very rare making an analysis of individual case series of limited value in judging their frequency and significance. In this regard it would be more powerful to know the results across a much broader spectrum of surgeons, and ideally across a whole nation [8,9]. A contemporary analysis of outcomes seems timely given the widespread changes in nephrectomy practice over the last decade viz the adoption of minimally invasive surgery, increased utilisation of nephron-sparing surgery, and cytoreductive nephrectomy in the era of tyrosine kinase inhibitors (TKIs).

In the first three years of data collection BAUS surgeons have entered data on over 20,000 nephrectomies. A detailed analysis of the deaths following these nephrectomies would potentially achieve the following objectives: firstly, establish accurately the contemporary risk of death following all types of nephrectomy [10]; secondly, identify and quantify risk factors associated with death; and thirdly, help understand more clearly the relationship between volume and outcome in nephrectomy.

Materials and Methods

A national database of selected procedures has been maintained by BAUS since 2001. Participation in this database was optional until 2012 when a government directive made it compulsory to record the outcomes of a selected index procedure [11]. BAUS chose nephrectomy as the index

operation and the existing BAUS database was modified to allow data entry on nephrectomy (e.g. ischaemia times, margins). All types of nephrectomy were included – radical, partial, cytoreductive, nephro-ureterectomy and simple nephrectomy.

BAUS members in England, Wales, Scotland and Northern Ireland entered data online on nephrectomies performed in 2012, 2013 and 2014. Data entry was mandatory in England and optional for Wales, Scotland and Northern Ireland. This dataset can be viewed at www.baus.org.uk/patients/surgical_outcomes and covers a period between 1st January 2012 and 31st December 2014. Data was entered on 21,380 nephrectomies. The operations were performed by 321 surgeons in 122 hospitals. In total, this represented 86% of all nephrectomies performed in England when compared to Hospital Episode Statistics (HES) [12]. Complications were graded according to the Clavien-Dindo classification.

BAUS initiated a retrospective analysis of data prospectively entered into the database to identify all deaths within 30 days of nephrectomy (TDM) and understand the risk factors behind those deaths. The latter was investigated using univariate and multivariate logistic regression analyses whereby TDM was the main outcome of interest. The multivariate models were adjusted for age, sex, performance status, and T-stage. In addition, we studied the TDM by surgeon and centre volume using mortality control charts.

Statistical analyses were conducted with Statistical Analysis Software (SAS) release 9.4 (SAS Institute, Cary, NC) and Microsoft Excel. Institutional review board approval was exempted as this data forms part of a compulsory National Audit run under the auspices of BAUS.

Results

Data on 21,380 nephrectomies was entered by 321 surgeons from 122 centres across the UK over the three year period. A total of 20,085 of the 22,824 (88%) nephrectomies performed in England were captured in this National Audit when compared with Hospital Episode Statistics (HES), which is available for England only. 94% of the data was entered by hand rather than being uploaded from a registry e.g. Somerset Cancer Registry. The median number of procedures per consultant was 13 (1-106) in 2012; 15 (1-118) in 2013; and 16 (1-133) in 2014, whereas the median number of procedures per centre was 35 (1-229) in 2012; 39 (1-295) in 2013; and 39 (1-286) in 2014.

Table 1 outlines the baseline characteristics of the patients by TDM status.

There were 110 TDMs (0.5%) observed. The underlying causes of death were recorded as follows: urological cancer (2/110;1.8%), cardiac (1/110;0.9%), pulmonary embolism (1/110;0.9%), respiratory (1/110;0.9%), not known (4/110;3.6%), non-urological cancer (1/110;0.9%); non-cancer (13/110;11.8%); not recorded (87/110;79.1%).

The univariate and multivariate odds ratios (OR) and 95% confidence intervals (CI) for TDM are shown in Table 2. The univariate analyses showed a statistically significant positive association with blood loss and transfusion, cytoreductive surgery, conversion, operative time, stage, age, and performance status. Upon adjustment for age, performance status, T-stage, and sex, these observations remained. The strongest associations were observed for blood loss, conversion, and technique: For instance, patients who lost between 2000-5000ml of blood as compared to those who lost <500ml had an OR of 3.92 (95%CI: 1.52-10.13). This OR became 39.70 (95%CI: 16.57-94.62) for those who lost more than 5000ml blood during the surgery (Table 2). TDM was higher in the group that lost 1-2L than in the 2-5L group (OR 1.38; 95% CI 1.03-2.24).

Those who underwent surgery with curative intent had a lower risk of TDM compared to those who underwent cytoreductive surgery (OR: 0.31 (95%CI: 0.18-0.54). An inverse association was noted for partial versus radical nephrectomy (OR: 0.32 (95%CI: 0.11-0.89).

Patients who underwent conversion to open surgery had a 2.53 higher risk for TDM, compared to those who did not (95%CI: 1.41-4.51) (Table 2). Reasons for conversions included bleeding (187/712; 26.3%), difficult dissection (174/712;24.4%), failure to progress (95/712;13.3%), size of tumour (59/712;8.3%), adhesions (50/712;7.0%), patient obesity (11/712;1.5%), and bowel perforation (5/712;0.7%). The reason was not recorded in 131/712(18.4%) cases. Of the 16 that died post-conversion the reasons for conversion were bleeding (6/187;3.2%), difficult dissection (4/174;2.3%), adhesions (2/50;2%) and not recorded in 4/16(25.5%) cases.

Open surgery was associated with a higher TDM than minimally invasive surgery (OR 1.69; 95% CI 1.13-2.53).

Finally, we analysed TDM by surgeon and centre volume (figures 1 and 2). The outliers above the 95% upper limit are those that are low volume.

Discussion

This study is based on an outstanding effort by an entire nation to prospectively and systematically determine the outcomes of all nephrectomy. Several elements suggest that surgeons in the UK are highly competent: the headline rate of death is 0.5% (110/21380); the safe introduction of minimal access surgery which now comprises approximately two-thirds of procedures performed with a mortality of 0.4% (59/14372); only four deaths were reported after 3931 partial nephrectomies (TDM 0.1%); and the mortality rate following nephrectomy for T3 disease was 0.8%. These are impressive results and stand comparison with rates published from the analysis of other large databases such as the National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) and the National Surgical Quality Improvement Program (NSQIP) databases which suggest overall mortality rates following nephrectomy of 0.9% and 1.13% respectively [13,14].

This study corroborates the importance of well-established risk factors associated with increased TDM: performance status (PS), T stage, blood loss and advanced age [15-17,4]. For example, there was a 4-fold increase in the risk of death for WHO PS 2 compared to 0, and a 16-fold increase between PS 4 and PS 0. TDM following surgery for T4 tumours was 10-fold greater than T1 and T2 tumours. Heavy blood loss >5Litres was associated with a 33-fold increased risk of death compared to <500mls.

The pan-national data in this study has allowed quantification of the contemporary risk of death following each type of nephrectomy that could be valuable information for inclusion in the consent forms generated by BAUS and used as a benchmark against which individual surgeons may choose to measure themselves. TDM rates following radical, partial, simple nephrectomy and nephro-ureterectomy are 0.6% (63/11057), 0.1%(4/3931), 0.4% (11/2819) and 0.9% (28/3091) respectively. Higher TDM following nephro-ureterectomy was significant on univariate but not multivariate analysis suggesting that the difference is likely to be due to patient co-morbidity/PS rather than the operation itself or tumour characteristics. Minimally invasive surgery appears to have been introduced safely with no associated increase in mortality risk. In fact it appears open surgery may be more risky. TDM following open surgery is double that of minimally invasive surgery [47/5863 (0.8%) compared to 59/14372 (0.4%); OR 1.69; 95% CI 1.13-2.53]. This is most likely to be due to unmeasured confounding factors; information with regard to whether patients had prior surgery, their body mass index, whether surgery was emergency or elective, are not included in this analysis and may offer explanations as to why open nephrectomy appears have a higher TDM than minimally invasive surgery. An additional contributory factor may be that training in open

surgery in the UK is difficult to access and does not form part of the core curriculum for UK urological trainees.

Whilst blood loss has previously been identified as a risk factor for death [4,16], this study allows a more detailed analysis of the relationship between blood loss and mortality. Intuitively one might imagine that only very heavy blood loss (e.g. >2 litres) might be dangerous but that does not appear to be the case. This study suggests that an estimated blood loss (EBL) of 1-2L is more dangerous than EBL of 2-5L. EBL of 1-2L is associated with a 6-fold increased risk of death compared to EBL <500 mls, whereas EBL of 2-5L is associated with a 4-fold increased risk. This seems counter-intuitive. This may reflect the difficulty of estimating blood loss accurately; it may be that the 1-2L category is too wide and the majority of cases in this category in fact have blood loss closer to 2L than 1L; or it may be that quite modest loss (1-2L) is when patients have adverse physiological consequences but not the same aggressive management as a patient with >2L blood loss would receive e.g. transfusion, invasive monitoring, and management in a high-dependency unit. More accurate measures of cardiac output during major surgery using trans-oesophageal Doppler might be the key to intra-operative monitoring of the physiological responses to blood loss [18].

TDM following conversion from minimally invasive to open surgery was significantly higher than those that were not converted (OR 2.53; 95%CI: 1.41-4.51). Potential explanations could be grouped into three: the events leading to conversion, the quality of open nephrectomy then performed; and post-operative care [17,19]. The common reasons for conversion include bleeding, adhesions and difficult dissection. It may be that, on occasion, a trial laparoscopic dissection was attempted to assess feasibility of minimally invasive nephrectomy prior to planned conversion – 8% (59/712) conversions due to size of tumour. The BAUS Section of Oncology has commissioned a detailed review of the cases that were converted so that we can make stronger recommendations about the safe management of conversions. This is a research priority.

The relationship between volume of surgery and mortality is of interest but must be interpreted with caution. Several low-volume surgeons and centres reported no deaths. Most surgeons / centres that reported deaths reported only one death and one death inevitably looks more significant if the case volume is low. Equally a surgeon / centre may have a clustering of deaths due to chance rather than underperformance [20], however the likelihood of this is reduced over three years of data collection. The appropriate response to outliers is not clear but without doubt is an organisational priority for BAUS and is one of the main reasons the directive was issued by the government. Despite looking at a dataset of over 20,000 nephrectomies, mortality is so low that it does

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not appear to provide a reliable measure of surgical quality or a basis for strong conclusions that might inform policy-making.

Limitations of this study centre around data capture, data entry and the endpoints measured.

Firstly, cross-referencing with Hospital Episode Statistics (HES) [12], which is available for England only, suggests that we captured 20,085 of the 22,824 (88%) nephrectomies performed by English surgeons between 2012-2014 and 107 of the 166 deaths that occurred (64%). This could partly be attributed to the fact that only Urologists contributed data to the BAUS audit but HES data records nephrectomies performed by all surgeons including transplant and trauma surgeons. Encouragingly the data capture has improved from 78% in 2012 to 94% in 2013 and 86% in 2014, with 69% of deaths in the UK in 2014 captured compared to 58% in 2012.

Secondly, the data was surgeon reported and all surgeons were mandated to provide it. Clinical epidemiologists question the value of surgeon reported data particularly with respect to the reporting of complications but it seems surgeons are ideally placed to report operative data most effectively. The time-scale on the directive from the government for this first 2012 study was extremely short with only 4 months from announcement of the initiative to the publication of results and over following years the quality of data has and should continue to improve [3,21] with reduction in the number of gaps in the data. In time it maybe that the quality of reports will be something that needs to be verified by independent auditors.

Thirdly, is mortality the most valuable outcome to measure when addressing the quality and safety of nephrectomy in the UK? Whatever its merit as an endpoint, death is clinically relevant, it is verifiable, and it is unarguable.

An overriding strength of this study is the demonstration that meaningful national data entry is feasible and is a valuable tool both for informing current practice and for improvement strategies within a surgical specialty. Hand entry of data, rather than from administrative datasets, is also likely to yield more meaningful conclusions. A future recommendation would be for a root-cause analysis to be carried out for all deaths in order to better understand all the individual patient, tumour and surgical factors involved in death from nephrectomy. As completeness of data improves it may also become possible to perform time-to-event analyses and generate predictive individual patient scores.

Conclusion

This analysis of deaths occurring after nephrectomy in the UK over three years has given fresh fascinating insights into the risks of nephrectomy. It can help inform consent and provides contemporary TDM for all types of nephrectomy. The quality of surgery in the UK appears high. In addition to confirming established risk factors this study identifies surgery causing modest blood loss (1-2L) and conversions as areas of clinical and research priority. Those surgeons / centres with the highest TDM appear to be those performing low volume surgery. Outliers could be identified and assessed in an effort to improve national nephrectomy practice.

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Table 1. Baseline patient, tumour and operative characteristics by 30-day status		
	Death (n=110)	Alive (n=21,270)
Mean age (SD), years	70.59 (12.02)	62.02 (14.00)
Sex		
Male	70 (63.64)	12269 (57.68)
Female	37 (33.64)	8526 (40.08)
Unrecorded	3 (2.73)	475 (2.23)
WHO Performance Status		
0	24 (21.82)	9469 (44.52)
1	37 (33.64)	5742 (27.00)
2	30 (27.27)	1672 (7.86)
3	7 (6.36)	308 (1.45)
4	2 (1.82)	50 (0.24)
Unrecorded	10 (9.09)	4029 (18.94)
Pathological T stage		
T1-2	28 (25.45)	8961 (42.13)
T3-4	52 (47.27)	5215 (24.52)
Unrecorded	30 (27.27)	7094 (33.35)
Side		

Left	74 (67.27)	15016 (70.60)
Right	35 (31.82)	6135 (28.84)
Bilateral	1 (0.91)	109 (0.51)
Unrecorded	43 (39.09)	9337 (43.90)
Procedure		
Radical nephrectomy	63 (57.27)	10994 (51.69)
Partial nephrectomy	4 (3.64)	3927 (18.46)
Simple nephrectomy	11 (10.00)	2808 (13.20)
Nephroureterectomy	28 (25.45)	3063 (14.40)
Other	4 (3.64)	294 (1.38)
Unrecoded	0 (0.00)	184 (0.87)
Conversion		
Yes	16 (14.55)	696 (97.75)
No	44 (40.00)	13789 (64.83)
Unrecorded	50 (45.45)	6785 (31.90)
Cytoreductive		
Yes	18 (16.36)	957 (4.50)
No	76 (69.09)	16488 (77.52)
Unrecorded	16 (14.55)	3825 (17.98)

Operative time		
<60min	0 (0.00)	545 (2.56)
1-2 hours	13 (11.82)	5078 (23.87)
2-3 hours	34 (30.91)	7622 (35.83)
3-4 hours	25 (22.73)	3517 (16.54)
4-6 hours	16 (14.55)	1452 (6.83)
>6 hours	8 (7.27)	157 (0.74)
Unrecorded	14 (12.73)	2899 (13.63)
Measured blood loss		
<500ml	49 (44.55)	15308 (71.97)
500-1000ml	12 (10.91)	1535 (7.22)
1000-2000ml	17 (15.45)	654 (3.07)
2000-5000ml	5 (4.55)	281 (1.32)
>5000ml	8 (7.27)	49 (0.23)
Unrecorded	19 (17.27)	3443 (16.19)
Units of blood transfused		
0	55 (50.00)	17016 (80.00)
<2	11 (10.00)	881 (4.14)
2-6	15 (13.64)	469 (2.20)

>6	10 (9.09)	118 (0.55)
Unrecorded	19 (17.27)	2786 (13.10)
Diagnosis		
Malignant	90 (81.82)	16525 (77.69)
Non-malignant	14 (12.73)	3708 (17.43)
Unrecorded	6 (5.45)	1037 (4.88)

Table 2. Univariate and multivariate logistic regression model for TDM		
	Univariate OR (95%CI)	Multivariate* OR (95%CI)
Age, years	1.06 (1.04-1.08)	1.04 (1.02-1.06)
Sex		
Male	1.00 (Ref)	1.00 (Ref)
Female	0.76 (0.51-1.13)	0.78 (0.52-1.16)
WHO Performance Status		
0	1.00 (Ref)	1.00 (Ref)
1	2.54 (1.52-4.25)	1.73 (1.02-2.96)
2	7.08 (4.13-12.14)	4.27 (2.42-7.53)
3	8.97 (3.83-20.97)	5.65 (2.38-13.41)
4	15.78 (3.63-68.57)	17.32 (3.91-76.82)
Pathological T stage		
T1-2	1.00 (Ref)	1.00 (Ref)
T3-4	3.19 (2.01-5.06)	2.50 (1.57-3.98)
Side		
Left	1.00 (Ref)	1.00 (Ref)
Right	1.16 (0.77-1.73)	1.08 (0.72-1.62)
Bilateral	1.86 (0.26-13.51)	2.32 (0.31-17.27)
Procedure		

Radical nephrectomy	1.00 (Ref)	1.00 (Ref)
Partial nephrectomy	0.18 (0.07-0.49)	0.32 (0.11-0.89)
Simple nephrectomy	0.68 (0.36-1.30)	1.12 (0.51-2.48)
Nephroureterectomy	1.60 (1.02-2.49)	1.10 (0.69-1.74)
Other	2.37 (0.86-6.57)	2.59 (0.90-7.49)
Converted		
Yes	3.12 (1.77-5.51)	2.53 (1.41-4.51)
No	1.00 (Ref)	1.00 (Ref)
Cytoreductive		
Yes	1.00 (Ref)	1.00 (Ref)
No	0.45 (0.15-0.41)	0.31 (0.18-0.54)
Operative time		
<2 hours	1.00 (Ref)	1.00 (Ref)
2-4 hours	2.29 (1.26-4.18)	2.07 (1.13-3.79)
>4 hours	6.45 (3.28-12.70)	4.98 (2.49-9.96)
Measured blood loss		
<500ml	1.00 (Ref)	1.00 (Ref)
500-1000ml	2.44 (1.30-4.60)	1.88 (0.99-3.58)
1000-2000ml	8.12 (4.65-14.18)	6.62 (3.73-11.74)
2000-5000ml	5.56 (2.20-14.06)	3.92 (1.52-10.13)

>5000ml	51.01 (22.96-113.32)	39.70 (16.57-94.62)
Units of blood transfused		
0	1.00 (Ref)	1.00 (Ref)
<2	3.86 (2.02-7.41)	2.56 (1.32-4.97)
2-6	9.90 (5.55-17.64)	6.60 (3.64-11.98)
>6	26.22 (13.05-52.68)	17.07 (8.11-35.95)
Intraoperative complications		
Yes	1.00 (Ref)	1.00 (Ref)
No	0.09 (0.06-0.14)	0.11 (0.07-0.17)
Postoperative complications		
Yes	1.00 (Ref)	1.00 (Ref)
No	0.03 (0.01-0.04)	0.03 (0.02-0.06)
Diagnosis		
Malignant	1.00 (Ref)	1.00 (Ref)
Non-malignant	0.69 (0.39-1.22)	1.33 (0.60-3.00)

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