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1 **Raised pre-operative INR identifies patients at high risk of peri-operative death**
2 **after simultaneous renal and cardiac surgery for tumours involving the peri-**
3 **diaphragmatic inferior vena cava (IVC) and right atrium.**

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21 **Abstract**

22 **Background** The ability to predict and therefore avoid surgery in those patients likely to die
23 from simultaneous renal and cardiac surgery for urological tumours involving the peri-
24 diaphragmatic vena cava and right atrium would be valuable.

25 **Objective** To identify pre-operative factors that predict thirty-day mortality (TDM) in patients
26 undergoing this type of surgery.

27 **Design setting and participants** Retrospective review of peri-operative outcomes in patients
28 managed between December 2007 and January 2016 by a single team.

29 **Outcome measurements and statistical analysis:** Relationships with outcome analysed using
30 Fisher's Exact and Mann Whitney U tests.

31 **Results and Limitations:** 46 patients of whom 41/46 (89%) underwent surgery

32 20 males; 21 females . Median age 65 yrs (range 17-95). 37 renal cell cancer, 1 adrenal cancer, 2
33 primitive neuroectodermal tumours and 1 leiomyosarcoma.

34 Overall TDM 3/41 patients (7%). INR, age and eGFR correlated significantly with TDM.

35 Mortality if INR >1.5, 3/5 (60%) compared to 0/36 (0%) if INR <1.5.

36 Mortality if INR >1.5 and age >70 years 3/3 (100%)

37 INR correlated with serious complications ($\geq$ Clavien 3) (INR>1.5: 5/5 (100%) vs INR<1.5: 12/36
38 (33%); $p<0.002$).

39 Median eGFR in those that died was 36 (range 26-37) compared to 52 (range 24-154) in those
40 that survived ($p=0.018$).

41 Limitations include retrospective design

42 **Conclusions:** Combined cardiac and renal surgery is associated with high risk of TDM when the
43 preoperative INR is abnormal and the patient is elderly. Surgery in patients with a normal INR is
44 challenging but safer.

45 **Patient summary:** When kidney tumours invade the inferior vena cava and the heart, blood
46 coagulation may become very abnormal (raised INR). Simultaneous cardiac and renal surgery
47 appears very high risk if the pre-operative INR is raised, particularly in the elderly. The surgery
48 appears much safer if the pre-operative INR is normal.

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60 **Introduction**

61 Growth of renal cancer into the retro-hepatic IVC and onwards into the right atrium presents a
62 considerable circulatory and oncological challenge. Patients may be very short of breath due to
63 the circulatory compromise; venous return may be reduced; right atrial function sub-optimal;
64 embolism of tumour may further impair cardio-pulmonary function; there may be very marked
65 swelling of the abdomen and lower limbs limiting mobility; the mass of tumour itself may be
66 enormous; and metastasis at the time of presentation is common. Nevertheless the situation is
67 not hopeless and since the first reports of successful surgery in the 1970's [1,2] there has been
68 steady progress in our understanding of how best to manage the various challenges associated
69 with intra-caval and intra-cardiac renal cancer. When the tumour is in the right atrium the
70 combination of radical nephrectomy with intra-cardiac and retro-hepatic intravenous tumour
71 extraction under conditions of hypothermic total circulatory arrest on cardiopulmonary bypass
72 is one approach [3-6]. There does however continue to be debate about the necessity for
73 hypothermic arrest and even bypass in these situations, particularly when the cephalad extent
74 of venous invasion is supra-hepatic but not atrial [7]. Expert multidisciplinary intra-operative
75 care from cardiothoracic surgeons, cardiothoracic anaesthetists, and urologists combined with
76 post-operative intensive care allows the surgery to be performed with acceptable morbidity
77 and mortality [8]. Nevertheless this combination remains one of the highest risk procedures in
78 urological surgery with contemporary series reporting thirty-day mortality (TDM) of
79 approximately 11% [6].

80 Understanding who is most at risk of TDM would be a major step forward in the management
81 of this condition. The surgery could then be offered selectively to those most likely to gain
82 benefit from it. Other patients who were considered unlikely to survive the surgery or its

83 aftermath might be better managed with drugs or palliative approaches. This would also mean
84 that this very expensive care could be concentrated on those likely to derive benefit from it.
85 The question of who to offer surgery to has been made more pertinent by the introduction of
86 drugs which are active in renal cancer [9]. This is for two reasons viz, firstly, the drugs may be
87 an alternative to surgery altogether; and secondly, the drugs make control of metastatic
88 disease a possibility thus opening up the whole field of complex intra-cardiac surgery in more
89 advanced oncological situations or even cytoreductive settings.

90 Abel et al [6] in a recent multicentre collaborative review of outcomes from several centres in
91 the USA highlighted performance status and serum albumin as key determinants of peri-
92 operative outcomes although neither could absolutely discriminate between those destined to
93 die from complications arising from surgery and those destined to do well. Other recent reports
94 suggest that the surgical Apgar score [10] may help identify patients at high risk of
95 complications post-nephrectomy. The ideal test would be one that could be applied pre-
96 operatively and would be both highly sensitive and specific for predicting adverse peri-
97 operative outcomes.

98 In 2007 we established a programme in our hospitals for the management of these complex
99 intra-cardiac renal tumours. Two urological surgeons and one cardiothoracic surgeon and one
100 cardiothoracic anaesthetist have been part of the core surgical team. Our approach since
101 inception of the programme has been inclusive, i.e. to err on the side of offering surgery rather
102 than selecting out only lower risk candidates, often because surgery seemed to represent a
103 patients only hope and because patients were often so symptomatic from the disease burden.
104 In that time 46 patients have been referred to our team; 41 patients have undergone surgery,

105 and only 5 patients have been managed in other ways. Now in 2016 we report the key lessons
106 we have learned over that 8 year period regarding peri-operative risk.

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123 **Methods**

124 This study is a review of peri-operative outcomes and TDM in all patients who have undergone
125 simultaneous cardiac and renal tumour surgery between December 2007 and May 2015 at our
126 centre. A full review of electronic and paper records was undertaken. All operative records had
127 been filed prospectively.

128 The surgery was performed in the cardiothoracic units of St Thomas Hospital or London Bridge
129 Hospital. The core team has comprised two urological surgeons, one cardiothoracic surgeon
130 and one cardiothoracic anaesthetist. Patients underwent general anaesthesia; position was
131 supine; incision median sternotomy with Mercedes Benz extension to the abdomen; early
132 ligation of renal artery; full renal mobilisation; full mobilisation of right hepatic lobe; IVC
133 mobilisation with division of caudate lobe branches; heparinisation and establishment of
134 cardiopulmonary bypass with cooling to 22C and circulatory arrest for ~20minutes (if required);
135 complete removal of tumour; IVC repair/grafting (if required); re-establishment of circulation;
136 warming to 37C; wound closure. Patients were admitted either to overnight theatre recovery or
137 intensive care at the discretion of the team.

138 A number of potentially important pre and peri-operative variables were studied. These were
139 then compared between patients who survived and patients who died in the perioperative
140 period (30 days). Significance was determined using the Fisher's Exact or Mann Whitney U-test.
141 As there were only three peri-operative deaths, non-parametric logistic regression was used to
142 identify which of these variables were statistically significantly associated with TDM. With
143 respect to INR, no further stratification or adjustments were made due to the occurrence of
144 quasi-complete and complete separation.

Complications were categorised according to the Clavien Dindo classification [11]. A secondary univariate analysis was performed to identify potential risk factors for serious complications (Clavien ≥ 3). Multivariate models were not possible due to the occurrence of quasi-complete and complete separation.

164 **Results**

165 46 patients were assessed. 41/46(89%) underwent simultaneous urological and cardiac surgery.
 166 5 patients did not undergo surgery (1 refused, 3 overwhelming metastatic load, 1 extreme
 167 frailty). 34/41 (83%) operations were performed with curative intent in the absence of
 168 radiological evidence of metastases. 7/41 (17%) cytoreductive. 3/41(7%) patients died in the
 169 perioperative period. Histology: 35 clear cell RCC; 2 papillary RCC; 1 adrenocortical carcinoma; 2
 170 primitive neuroectodermal tumour; 1 leiomyosarcoma.

171 Operative details are outlined in table 1. Post-operative complications are detailed by Clavien-
 172 Dindo classification in table 2. Overall, 30/41 (73%) patients had complications. 17 of these
 173 were $\geq$ Clavien 3 complications including 4 returns to theatre for bleeding and 1 for gastric
 174 perforation; 4 patients developed pulmonary emboli in the post-operative period and 4
 175 developed fast atrial fibrillation.

176 Baseline characteristics of those that died and those that survived are compared in Table 3.
 177 INR, age and estimated glomerular filtration rate (eGFR) were the only pre-operative variables
 178 that were statistically significantly associated with TDM. When conducting non-parametric
 179 logistic regression for INR (INR $\geq$ 1.5 vs $<$ 1.5) and perioperative death, we found an odds ratio
 180 (OR) of $+\infty$ (95%CI: 4.04 - $+\infty$) with a p-value of 0.001. Even though the occurrence of quasi-
 181 complete separation did not allow us to estimate the actual OR or the upper limit of the 95% CI,
 182 the lower limit of 4.04 indicates a strong positive association between an INR $\geq$ 1.5 and risk of
 183 TDM. As a result, no further adjustments for age or eGFR could be made.

184

185 Despite preoperative correction of INR, all 5 patients (100%) who had raised pre-operative INR
186 had serious complications ($\geq$ Clavien 3) (1 Clavien 3b, 1 Clavien 4b, 3 Clavien V), compared to
187 12/36(33%) of patients with normal INR ($p < 0.002$; table 2). The mortality for those with a raised
188 INR ≥ 1.5 was 3/5(60%) compared to 0/36 (0%) if the INR was normal. All 3 patients with a
189 raised INR who died were aged ≥ 70 years. 5/8(62%) patients aged ≥ 70 years survived; all five
190 had a normal INR.

191 A similar non-parametric logistic regression model was conducted for serious complications as
192 INR was the only risk factor showing an association in a multivariate analysis (table 4). When
193 conducting a non-parametric logistic regression for INR (INR > 1.5 vs ≤ 1.5) and Clavien ≥ 3 , we
194 found an OR of $+\infty$ (95%CI: 1.51 - $+\infty$), with a P-value of 0.008. Even though the occurrence of
195 quasi-complete separation did not allow us to estimate the actual OR or the upper limit of the
196 95%CI, the lower limit of 1.51 indicates a positive association between an INR ≥ 1.5 and risk of
197 serious complications.

198 The positive predictive value (PPV) of raised INR alone for death is 3/5 (60%). PPV of age ≥ 70
199 years is 3/8 (37.5%). PPV for combination of age ≥ 70 years and INR ≥ 1.5 was 3/3 (100%). None
200 of the 36 patients with a normal INR died. Negative predictive value (NPV) of normal INR 100%

201 Bloods loss; the use of cardiac bypass with or without arrest and cooling; whether the tumour
202 was above or below the diaphragm; abnormal liver profiles and albumin level; and performance
203 status were not statistically significantly associated with TDM.

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207 Discussion

208 Surgery for patients with renal tumours invading the peri-diaphragmatic IVC and/or right atrium
209 is high risk. This study suggests that surgery of this type is potentially dangerous if a patient's
210 pre-operative INR is abnormal. All 3 patients who died had an abnormal INR, despite the INR
211 being corrected prior to surgery. The overall thirty-day mortality (TDM) in patients with INR
212 ≥ 1.5 was 3/5(60%). The two patients with INR ≥ 1.5 who survived had serious complications
213 (Clavien 3b and 4b) and prolonged lengths of stay (62 and 70 days). Furthermore, this study
214 has shown that this surgery can be performed relatively safely in patients with normal INR. No
215 patients with a normal INR died in the post-operative period (TDM 0%).

216 It is of interest that the three patients who died in this series not only had an abnormal INR, but
217 were also aged over 70, whereas the two patients with an abnormal INR who survived surgery
218 were aged under 70 (aged 63 and 54 years). No patient over the age of 70 with an abnormal
219 pre-operative INR >1.5 has survived. Put another way, the PPV for TDM of the combination of
220 raised INR and age over 70 is 100%. This is important as it would suggest that elderly patients
221 who are already showing signs of metabolic compromise by virtue of raised INR do not have the
222 physiological reserve to survive the peri-operative challenge. The scale of the physiological
223 challenge must be the same in younger patients, but they may have more physiological reserve
224 to withstand it.

225 Age and eGFR were also shown to be important determinants of risk. An obvious question to
226 ask is, which is the most important risk factor– the INR, the eGFR or the age? Our data would
227 suggest very strongly the INR. All five patients over the age of 70 who had normal INR survived.
228 Furthermore, both younger patients with abnormal INR had very stormy post-operative
229 periods. With respect to eGFR, the median eGFR of those who survived was 52 compared to 36

230 in those who died. All three patients who died had an eGFR <40 and overall the mortality in
231 patients with an eGFR <40 was 3/8 (37.5%). Patients with a low GFR may be at increased risk of
232 peri-operative death. Constraints of time in the pre-operative period precluded formal
233 measurement of GFR (e.g. with chromium 51 labelled EDTA GFR) but might be of interest to
234 investigate this association further.

235 The reason the INR becomes abnormal in these patients is likely to be complex but probably
236 due to hepatocellular dysfunction arising as a consequence of congestion as a result of partial
237 hepatic venous obstruction. This in turn leads to ischaemia of parenchymal cells and deranged
238 production of clotting factors [12]. Alterations to coagulation parameters in these patients
239 seem to be a sign of advancing liver disease. Approximately 50% of our patients have abnormal
240 pre-operative liver enzymes (AST, ALT, Alkaline phosphatase) presumably indicating mild liver
241 dysfunction, but only 12% of these patients had progressed to have abnormal INR. It is also
242 interesting that despite all the patients with abnormal pre-operative coagulation having
243 aggressive pre-procedure corrective measures with vitamin K and fresh frozen plasma
244 infusions, major complications still transpired. The abnormalities signalled by a raised INR are
245 probably far more complex than those simply of coagulation; and rather indicate a metabolic
246 disorder which remains largely uncorrected despite the normalisation of coagulation. Equally
247 interestingly, the hepatic venous obstruction leading to the abnormal INR is not always
248 associated with clinical manifestations of the Budd-Chiari syndrome [12,13]. Only two of the
249 five patients with an abnormal INR had a clinical Budd-Chiari syndrome as evidenced by ascites.
250 None of the patients were jaundiced or encephalopathic.

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252 Should patients with an abnormal INR not be offered this type of surgery? Based on this study
253 we would exercise caution if the patient is elderly - as all three patients who had a raised INR
254 and were aged over 70 years died (mortality 100%). In younger patients with an abnormal INR,
255 we would still consider surgery if their background health was good prior to the tumour
256 presentation, and particularly if the patient was very symptomatic from the circulatory
257 disturbance; serious complications and a challenging post-operative period might be expected.
258 Furthermore, our work should not be viewed in isolation. Abel et al [6] suggested performance
259 status and serum albumin were also important factors associated with peri-operative
260 complications and TDM. In our series performance status (PS) was not statistically significantly
261 associated with TDM and deranged INR was a far more accurate predictor of mortality. We
262 speculate that reverse causation might explain why PS is not significantly associated with death
263 – rather than a reflection of underlying co-morbidity, poor PS may be a direct consequence of
264 circulatory obstruction or tumour volume, and therefore reversible with surgical correction. It
265 should also be noted that in the Abel series albumin levels were only available on 50% of the
266 patients making it difficult to be certain of the significance of the effect. One strength of our
267 study is that INR is available on all our patients.

268 This study is also very encouraging in demonstrating that combined cardiac and renal surgery
269 can be performed in patients with a normal INR with a low risk of TDM. None of our 36 patients
270 died. This may be valuable for optimising multidisciplinary clinical decision-making and for
271 counselling patients pre-procedure. The majority of patients despite feeling ill, having
272 compromised circulation and dyspnoea on exertion, and a large volume of tumour can be
273 steered through surgery successfully and have much to gain symptomatically from correction of
274 the circulatory problem. Nonetheless, the surgical and anaesthetic challenges are considerable

275 and success is only possible with a well-organised highly committed skillful team. In the context
276 of this disease this is also a high volume team.

277 Despite overall TDM being low, complications are common in this group. Overall complications
278 occurred in 30/41(73%) with 17/41(42%) having $\geq$ Clavien 3 complications. Even in the group we
279 would now consider relatively low risk for peri-operative death (normal INR, <70yrs), the
280 complication rate was still 20/31(64%). INR appears to be a risk factor for predicting serious
281 complications (Clavien $\geq$ 3) as well as TDM.

282 This report is not considering the long-term oncological outcomes in this group of patients, but
283 it is known that the majority of patients with locally advanced renal cancer of this type will
284 develop systemic relapse [14,15]. The advent of multiple new medications for the control of
285 metastatic disease does, however, offer hope to patients if their heavily symptomatic loco-
286 regional disease can be controlled [16]. A particularly difficult scenario is to know whether this
287 type of surgery should be offered in cytoreductive settings [17,18]. A heavy burden of
288 metastatic disease would in most instances disqualify a patient, but a low volume of metastatic
289 disease in a younger patient, who has a normal INR and who is symptomatic from the
290 circulatory disturbance, might be considered a reasonable candidate for cytoreductive surgery.

291 The main limitation of this study is size making it difficult to draw stronger conclusions.

292 However given the frequency of this tumour our single institution data is still clinically
293 informative. Future study of the association between INR and TDM across wider groups of
294 patients, and particularly in national audits of nephrectomy [19], may provide a larger number
295 of events allowing for the calculation of multivariate logistic regression models. Moreover, our
296 data can now inform sample size calculations for these future studies.

297 Conclusion

298 In patients undergoing simultaneous renal and cardiac surgery for renal cancer, a raised pre-
299 operative INR appears to be a predictor of thirty-day mortality in elderly patients (≥ 70 years)
300 and of significant post-operative complications in younger patients (< 70 years). The surgery can
301 be offered with more confidence to patients with a normal INR.

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Tables

Table 1. Operative details (n=41)

Cardiac bypass	31 (76%)
Arrest + cooling	27 (66%)
Median blood loss in mls (min-max)	2250 (300-20000)
Median Operation time in hours (min-max)	5 (2.25-7.5)
Median length of stay in days (min-max)	16 (7-97)

Table 2. Complications by INR

	INR < 1.5 (n=36)	INR ≥ 1.5 (n=5)	P value
Clavien-Dindo Classification			0.002
0	11 (31)	0 (0)	
1	2 (6)	0 (0)	
2	11(31)	0 (0)	
3a	6 (17)	0 (0)	
3b	2 (6)	1 (20)	
4a	3 (8)	0 (0)	
4b	1 (3)	1 (20)	
5	0 (0)	3 (60)	

Table 3. Risk factors for serious complications

	Clavien <3 (n=24)	Clavien ≥3 (n=17)	P-value
Median age (min-max)	64.73 (31.00-95.00)	68.00 (17.00-76.00)	0.584
Sex			0.086

Male	9 (37.50)	11 (64.71)	
Female	15 (62.50)	6 (35.29)	
Karnofsky performance status			0.258
20	0 (0.00)	2 (11.76)	
30	0 (0.00)	1 (5.88)	
40	0 (0.00)	1 (5.88)	
50	2 (8.33)	2 (11.76)	
60	3 (12.50)	0 (0.00)	
70	6 (25.00)	5 (29.41)	
80	8 (33.33)	3 (17.65)	
90			0.258
Symptomatic	11 (45.83)	10 (58.82)	0.412
Curative	18 (75.00)	16 (94.12)	0.109
Above diaphragm	21 (91.30)	15 (88.24)	0.749
Bypass	16 (66.67)	15 (88.24)	0.113
Cooling	14 (58.33)	13 (76.47)	0.228
Median EBL (min-max)	2000 (100-5000)	3000 (30-2000)	0.157
Median Hb (min-max)	10.90 (10.00-87.00)	12.00 (9.00-13.00)	0.357
Median CRP (min-max)	35.50 (26.00-49.00)	37.00 (5.00-312.00)	0.598
Median INR (min-max)	1.00 (0.90-1.30)	1.00 (1.00-3.00)	0.033
Abnormal LFTs	8 (33.33)	10 (58.82)	0.105
Median albumin (min-max)	35.50 (26.00-49.00)	40.00 (26.00-50.00)	0.255
Median creatinine (min-max)	95.00 (54.00-180.00)	111.00 (17.00-	0.235
Median GFR (min-max)	52.50 (54.00-180.00)	46.00 (24.00-150.00)	0.910

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