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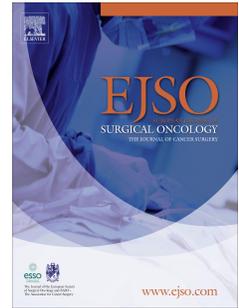
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**Evidence for a synchronous operative approach in the treatment of colorectal cancer with hepatic metastases: a case matched study.**

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## Abstract

### Background

Traditionally, a staged operative approach has been used for patients with synchronous colorectal cancer and liver metastases in the U.K. With improved outcomes from hepatic resection the role of a synchronous operative approach needs re-evaluated.

### Methods

32 consecutive patients with colorectal cancer and hepatic metastases that underwent a synchronous operative approach were individually case matched (according to: age; sex; ASA grade; type of hepatic and colonic resection) with patients that had undergone a staged approach. The following variables were analysed: operative blood loss; in hospital morbidity and mortality; duration of hospital stay; disease free and overall survival.

### Results

Operative blood losses were: synchronous group, median 475mL (range 150-850mL) vs median 425mL (range 50-1700mL), ( $p>0.050$ ). There were no significant differences in morbidity: (34% synchronous group vs 59%,  $p=0.690$ ) with no recorded mortality. Synchronous group had a shorter hospital stay (median 12 days [range 8-21] vs 20 [range 7-51],  $p=0.008$ ). There were no statistical differences between synchronous and staged patients for disease free and overall survival: 10 months (95% CI 5.8 – 13.7) versus 14 (95% CI 12.2 – 16.3);  $p=0.487$ ) and 21% versus 24% at 5 years ( $p=0.838$ ).

### Conclusion

This present study provides supporting evidence for synchronous operative procedures in patients with colorectal liver metastases.

## Introduction

Synchronous colon cancer with liver metastases presents a unique opportunity to deal simultaneously with both the primary and secondary disease. With at least 25% of patients with colorectal cancer presenting with liver metastases at time of initial diagnosis, there is potential to perform combined hepatic and colonic resections, as well as local ablative techniques at the same laparotomy<sup>1</sup>. This synchronous operative approach offers the advantage to the patient of a single laparotomy and hospital stay, allowing early instigation of aggressive adjuvant therapy when indicated. In addition, one hospital stay is likely to be more cost effective than the traditional staged approach with up to twelve weeks, the usual interval, between colonic resection and hepatic resection.

Despite these potential advantages, the staged approach remains the standard policy in most colorectal units in the United Kingdom. This is primarily based on evidence from earlier studies that suggested a significantly higher morbidity and mortality in patients undergoing synchronous resections compared to a staged approach<sup>2-6</sup>. Indeed, one study reported mortality as high as 17% in patients undergoing synchronous resections<sup>7</sup>.

The quality of hepatic surgery has improved greatly over the last two decades with advances in surgical and anaesthetic techniques, as well as radiological imaging, leading to improved short and long term outcomes<sup>8-11</sup>. Furthermore, with the introduction of radiofrequency (RF) ablation<sup>12-14</sup> and other ablative techniques, the traditional exclusion criteria of bilobar disease and multiple hepatic metastases are no longer absolute contraindications to performing partial hepatectomy. As a result, attention has turned

again to the role of synchronous resections, where caution is still advised especially if major colonic or hepatic surgery is being considered<sup>15,16</sup>.

It has been the policy in this small volume surgical department to pursue a synchronous operative approach in the treatment of metastatic colorectal cancer. To determine short and long term patient outcomes, this study cased matched patients undergoing synchronous procedures to patients undergoing staged procedures.

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## Methods

### Patients

Ethical approval for this study was obtained from the local research and ethics committee. Thirty two consecutive patients with colorectal cancer and hepatic metastases that underwent a synchronous operative approach (synchronous group) were individually case matched with patients that had undergone a staged approach (staged group). The patients in the staged group had their colonic resection performed at another hospital and were subsequently referred to this unit for treatment of their hepatic metastases.

Patients were case matched according to: age; sex; ASA grade (American Society of Anesthesiologists); type of hepatic resection and type of colonic resection. TNM stages were compared to ensure similar pathological staging between the two groups. In addition, the Clinical Risk Scores were calculated for each patient. This prognostic score has been developed for patients with colorectal liver metastases and inclusion in this study allowed further comparison between the synchronous and staged groups.

The criteria for selection for synchronous surgery have been documented previously and included: fitness for anaesthesia; expected margin negative resection (R0) of the primary disease; no unresectable extrahepatic disease and adequate predicted volume of hepatic remnant post resection<sup>17-20</sup>. Preoperative staging included contrast-enhanced CT and/ or MRI with intraoperative unenhanced and contrast enhanced ultrasound routinely performed<sup>21,22</sup>. In patients with synchronous disease, all were considered for synchronous resections according to the above mentioned criteria, irrespective of the type of colonic or hepatic resection that would be required.

### **Operative approach**

All procedures in the synchronous group were performed by a single consultant surgeon (PGH), anaesthetist (DS) and radiologist (EL). The type of hepatic resection was classified as: right lobectomy (Couinaud's segments V, VI, VII and VIII); left lobectomy (segments II, III and IV); bisegmentectomy; monosegmentectomy and non-anatomical subsegmentectomy<sup>23</sup>.

Intraoperatively, the large bowel was resected first through an appropriately sited midline incision with closure of the laparotomy wound prior to commencing hepatic resection via a subcostal incision. Often, a right hemicolectomy and hepatectomy could be performed via a single subcostal incision. Partial hepatectomy was performed using a triphasic approach: preoperative active dehydration; intraoperative CVP less than 5 cm H<sub>2</sub>O and continuous selective vascular occlusion (the half Pringle)<sup>18,20,24,25</sup>. Intraoperative blood loss (mL) was measured by adding the suction bottle volume to the increase in weight of surgical packs and swabs. In patients undergoing combined hepatic procedures, the hepatic resection was performed first, followed by RF ablation. RF ablation, using a water tip cooled system of 1-3 needles as required, was performed under ultrasound guidance (both unenhanced and enhanced) to both target the metastasis and to assess the ablation necrosis zone intraoperatively.

### **Follow up of patients**

Postoperatively, patients entered the departmental surveillance programme. This consisted of serial examination and contrast-enhanced CT at six months, then at yearly intervals, up until five years after their operation. Colonoscopies were performed at one

year, three years and five years after colonic resection. Patients that had undergone RF ablation had one additional scan at 6 weeks to allow confirmation of complete necrosis.

### **Outcome variables**

The following variables were analysed in the synchronous group and compared to combined values from both the initial colorectal resection and subsequent hepatic surgery from the staged group: operative blood loss; in hospital morbidity and mortality; duration of hospital stay; time to recurrence and long term survival.

Thirty day morbidity and mortality were standardised using a published grading system<sup>26</sup>. Grade 0 represents no complications. Grade 1 complications resolve spontaneously or with minimal intervention i.e. antibiotics, bowel rest. Grade 2 requires moderate intervention i.e. intravenous medication, chest drain insertion. Grade 3 graded complications require surgical or radiological intervention or readmission to hospital. Grade 4 is scored when patients are left with a long standing disability, organ resection or enteral division. Grade 5 represents death. Overall, minor complications are grouped as grades 1 to 2 and major complications 3 to 5.

## Results

There were no statistical differences found between the synchronous and staged groups for age, sex and ASA grade. In addition, there were no differences in TNM staging and Clinical Risk Score between the two groups with similar numbers of patients having undergone chemotherapy and/ or radiotherapy (Table 1). Seventy-eight percent of colorectal operations were classified as major resections with 22% major hepatic resections performed (Table 2). RF ablation was performed in six patients (five synchronous patients and 1 staged patient), with only one liver metastasis ablated in each case.

### Intraoperative blood losses

The median operative blood loss in the synchronous group was 475mL [mean 488mL (range 150-850mL)] versus median loss of 425mL [mean 574mL (range 50-1700mL)] for staged group ( $p>0.050$ ). No patient returned to theatre with postoperative bleeding.

### Postoperative outcomes

There were no significant differences in morbidity:  $n=11$  synchronous group versus  $n=19$  in the staged group (34% vs 59%,  $p=0.690$ ). There was no recorded mortality. Table 3 shows the morbidity recorded within the synchronous group, 10 out of the 11 complications were classified as minor. The synchronous group also had a significantly shorter hospital duration (median 12 days [range 8-21] vs 20 days [range 7-51],  $p=0.008$ ).

**Long term outcomes**

There were no statistical differences in disease free and overall survival. The median time to cancer recurrence in the synchronous group was 10 months (95% CI 5.8 – 13.7) versus 14 months (95% CI 12.2 – 16.3);  $p=0.487$ ) in the staged patients. The overall median survival of the synchronous versus the staged patients was 39 months versus 42 months and 21% versus 24% at 5 years (log rank  $p=0.838$ ).

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## Discussion

The evidence for performing staged colonic and hepatic resections comes from several earlier studies that suggested an associated greater blood loss, higher morbidity and higher mortality with synchronous surgery<sup>2-4,6</sup>. However, the majority of these studies were performed before the time frame of significant improvements in patient outcomes with hepatic resection. In addition, it is difficult to evaluate these early studies as there was no accepted definition of the term synchronous resection. For some authors, this was classified as hepatic resection at the time of laparotomy for the colonic primary. For others, the term synchronous referred to resection of the hepatic metastases up to three months after the primary bowel surgery.

### Evidence supporting synchronous resections

Recent studies have been published that overcome some of the limitations of the earlier studies. Chua et al (2004) retrospectively analysed 96 patients that presented with colorectal cancer and liver metastases<sup>15</sup>. These patients underwent either synchronous (n=64) or staged bowel and hepatic resections (n=32) within the same surgical unit. For analysis of outcomes in the staged group, variables from both the primary and secondary surgery were added together and compared with the synchronous resections group. The results showed a trend towards lower volume liver resections (p=0.09) with an increased blood transfusion rate after synchronous resections (mean 326mL vs 185mL, p=0.08). Postoperative complication rates were similar between groups (53% synchronous vs 41% staged, p=0.25) with no operative mortality. The synchronous group experienced a significantly shorter hospital stay (mean 11 vs 22 days; p=0.001). In relation to long term outcomes, no significant differences between groups (synchronous vs staged) in disease

free survival or overall survival were found (median 13 vs 13 months,  $p=0.53$ ; median 27 vs 34 months,  $p=0.52$ ).

Martin and colleagues from the Memorial Sloan-Kettering Cancer Centre performed a similar analysis from a prospective database over a 17 year period<sup>27</sup>. One hundred and thirty four patients (group I) underwent synchronous resections, whilst 106 patients underwent staged resections (group II). Again, the extent of hepatic disease was less in the synchronous resections group (fewer number of tumours,  $p=0.001$ ; smaller tumours,  $p=0.009$ ) resulting in significantly lesser hepatic resections being performed (major resections 34% group I vs 72% group II,  $p=0.001$ ). In addition, right hemicolectomy was performed in 40% of synchronous resections compared to only 14% in staged resections. Although the blood loss was significantly greater in group II, there was no difference in transfusion rates between groups. Regarding postoperative complications, the synchronous resections had significantly less (49% vs 67%,  $p<0.003$ ) than group II, which on further analysis appeared to be a direct result of a second laparotomy in the staged group. This reduced complication rate also contributed to the significantly shorter hospital stay (median 10 vs 18 days,  $p=0.001$ ). Perioperative mortality was exactly the same in both groups ( $n=3$ ). Unfortunately this study did not analyse long term outcomes.

A retrospective multi-institutional analysis of 610 patients with colorectal liver metastases ( $n=135$  synchronous resections,  $n=475$  staged resections) is the largest study to date<sup>28</sup>. Again, they found that there were greater major colonic resections performed with larger hepatic resections in the staged group. In addition, staged patients were more likely to undergo local ablation with the hepatic resection. Hospital stay was significantly shorter in the synchronous group (median 9 vs 14 days) with morbidity and mortality not

statistically different between the two groups (overall morbidity 36.3% vs 38.6% for simultaneous vs staged respectively, with 14.1% vs 12.5% classified as severe; mortality 1.0% vs 0.5%). This study divided the groups into major and minor hepatic resections, documenting higher rates of severe morbidity when compared to the staged group, leading the authors to state that caution should be exercised before performing synchronous colonic with major hepatic resections.

### **Current study supports synchronous resections**

This present study provides further supporting evidence for the application of synchronous procedures in patients with colorectal liver metastases. This study overcomes some of the limitations of the studies referred to previously. Patients had no significant differences in age, sex and ASA. With no statistical differences in TNM staging and Clinical Risk Score we have compared groups with similar disease burdens. Furthermore, matching each synchronous patient according to the hepatic and colonic resection with a patient in the staged group removed any bias for performing lower volume hepatic resections and/or minor colonic resections in one group. In fact, 6 patients underwent combined major colorectal and major hepatic resections.

In agreement with Martin et al's results there were no significant differences in blood losses between the two groups<sup>27</sup>. Indeed the overall blood loss was low reflecting the advances in hepatic surgery and anaesthesia. In this study, there were no patients that had documented cirrhosis. Greater blood losses have been documented in cirrhotic patients undergoing partial hepatectomy and greater losses would be expected if they were to undergo synchronous operative procedures. As a consequence, it has been suggested that extreme caution should be applied before allowing these patients to undergo a

synchronous approach, with some authors stating that cirrhotic patients should be excluded<sup>24</sup>. In relation to patients that have undergone staged procedures to allow administration of chemotherapy, it has been shown that steatosis, steatohepatitis, and sinusoidal dilatation and congestion can result, leading to increased blood losses and increased morbidity after hepatic resection, although this was not clearly demonstrated in this study<sup>29,30</sup>.

This study did not find a significant difference in complication rates between the two groups (34% synchronous vs 59% staged). Indeed, all complications in the synchronous group, excluding one, were minor that resolved during the same hospital admission. It is worth highlighting that no patient developed an anastomotic leak which has been previously cited as a reason not to perform synchronous procedures. This study has also shown that major colonic resections can be performed safely as part of a synchronous approach and that they can be combined with major hepatic resections. In particular, rectal surgery which has been previously documented as a contraindication to synchronous surgery was performed in almost half the cases in this study<sup>16</sup>.

### **Long term outcomes not compromised by synchronous resections**

In relation to long term outcomes, no significant differences between groups in number of recurrences, disease free survival or overall survival were found. Although the study numbers were small, these results suggest that synchronous resections are safe and performing effective oncological surgery. One other area that needs further clarification is the long term outcomes after RF ablation. There are many studies stating that RF ablation is an effective and safe procedure for colorectal liver metastases, but many have focused on the technological aspects and short term outcomes only<sup>12,13,14</sup>. In this unit, we

find RF ablation a useful adjunct to surgical resection. It allows metastases that lie adjacent to major vessels to be ablated safely under ultrasound guidance.

The main limitation in this study was the small patient numbers, which is a reflection of the hospital involved being a small volume centre and not a specialist hepatobiliary centre. Both colonic and hepatic resections were performed by the same surgeon, demonstrating that the synchronous approach should be considered in all hospital settings. Ideally, a randomised trial in which the two groups were matched as in this study would provide definite answers about long term outcomes in this patient group, which continues to be the outstanding unanswered question.

### **Conclusion**

In conclusion, this study provides supporting evidence for the role of synchronous procedures in patients with colorectal liver metastases confirming that major colorectal resections can be safely performed in tandem with hepatic resections to provide effective oncological surgery.

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**Table 1:** Comparison of patient demographics, type of operation, pathological stage and chemotherapy/radiotherapy for synchronous and staged groups.

		synchronous (n=32)	staged (n=32)	P value
<b>Age</b>				
mean (range)		69 (53 – 79)	67 (37-82)	>0.05
<b>Sex</b>				
male: female		18:14	21:11	>0.05
<b>ASA</b>				
median (range)		2 (1-3)	2 (1-3)	>0.05
<b>Clinical Risk Score</b>				
median (range)		2 (1-3)	2 (0-5)	>0.05
<b>Bowel resection</b>				
	right hemicolectomy	7	7	
	left/ sigmoid colectomy	10	10	
	anterior resection	11	11	
	abdominoperoneal resection	1	1	
	Hartmann's procedure	3	3	
<b>T stage of primary</b>				
	T1	0	0	>0.05
	T2	2	4	
	T3	28	26	
	T4	2	2	
<b>N stage of primary</b>				
	N0	2	4	>0.05
	N1	21	20	
	N2	9	8	
<b>Type of hepatic resection</b>				
	subsegmentectomy	7	7	
	monosegmentectomy	9	9	
	bisegmentectomy	9	9	
	left hepatectomy	6	6	
	right hepatectomy	1	1	
<b>Radiofrequency ablation</b>		5	1	<0.05
<b>Chemotherapy/ radiotherapy*</b>		13	17	>0.05

\* denotes any type of neo-adjuvant and/or adjuvant chemotherapy and/ or radiotherapy.

**Table 2:** Summary of operative procedures in synchronous group.

	sub- segmentectomy	mono- segmentectomy	bi- segmentectomy	left hepatectomy	right hepatectomy	Total
<b>right hemicolectomy</b>	2	2	2	1	0	7
<b>Left/ sigmoid colectomy</b>	1	5	1	2	1	10
<b>anterior resection</b>	3	2	5	1	0	11
<b>abdominoperineal resection</b>	1	0	0	0	0	1
<b>Hartmann's procedure</b>	0	0	1	2	0	3
<b>Total</b>	7	9	9	6	1	32

Shaded areas represent major colorectal resections (n=25) and major hepatic resections (n=7).

*RF ablation –*

*N=3 sub/monsegmentectomy and anterior resection*

*N=1 monsegmentectomy and left/ sigmoidectomy*

*N=1 bisegmentectomy and anterior resection*

*N=1 bisegmentectomy and left/sigmoidectomy*

**Table 3:** Type and grade of postoperative complications recorded by synchronous and staged groups.

grade		synchronous group	staged group
1	wound infection	2	2
	UTI/ urinary retention	1	3
	ileus	1	3
	bile collection	2	2
	chest infection	0	5
	fluid overload	0	1
	C. Difficile	0	1
	Transfusion	0	1
	ARF	0	1
2	Chest tap/drain	1	0
	Atrial fibrillation	3	1
	Myocardial Infarction	0	1
3	readmission	1*	0
	<b>total</b>	<b>11</b>	<b>19</b>

\*Secondary to chest infection

- UTI – urinary tract infection
- *Clostridium difficile*
- Acute renal failure.