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Blood Transfusion has no Effect on Colorectal Cancer Survival. A Population-based Study

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This study was conducted to evaluate the impact on survival of perioperative blood transfusion in a series of 698 colorectal cancer patients undergoing radical surgery. Patients were identified, and follow-up was carried out by the local population-based cancer registry. Data on blood transfusion was obtained by record linkage with the files of the blood banks operating in the area covered by the registry. Prognostic factors were age, Dukes stage and topography of the primary tumour. Relative risk (RR) for Dukes B patients was 1.53 [95% confidence interval (CI) 0.94–2.50] and for Dukes C, 3.57 (95% CI 2.22–5.75) when compared with Dukes A patients. For the left colon, RR was 0.96 (0.61–1.52) and for the rectum 1.87 (1.22–2.86) when compared with the right colon. When adjusting for these factors and excluding operative mortality, RR for transfused patients was 1.16 (95% CI 0.87–1.55). It is concluded that blood transfusion does not adversely affect survival in colorectal cancer patients.
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INTRODUCTION

THE EFFECTS of blood transfusion on the survival or the duration of the disease-free interval in cancer patients has been extensively evaluated by means of retrospective studies, with inconclusive results. Several of the published studies are small and have limited statistical power to detect plausible differences in survival [1–7]. In other instances, the quality of the follow-up is unequal between recipients and non-recipients of blood transfusion [8] and several reports fail to consider key prognostic variables, making the comparison between studies impossible to interpret [1, 9]. Common to all hospital-based evaluations [1–13] is the selection of patients introduced by local health care referral systems which limits the interpretation of the results. All the mentioned studies used hospital-based data. Two recent large studies [14, 15] were multicentric.

In the island of Mallorca, a colorectal population-based cancer registry has been in operation since 1981, and conducts an annual active follow-up of all registered patients. The local blood banks keep records on all blood or blood product transfusions practised in the island for the period 1982–1987. It was therefore possible to link both registries and to evaluate the prognostic value of having received blood or a blood products transfusion at any given interval before or after surgery in an unselected large series of colorectal cancer patients.

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PATIENTS AND METHODS

Within the period 1 January 1982 to 31 December 1987, 1052 colorectal cancer patients were identified among the residents in the island of Mallorca by the Cancer Registry. Routine data collected for each patient includes: name, current address, date of birth, age at diagnosis, sex, tumour stage following the Dukes classification (A, B, C, metastasis), tumour topography (codes 153 and 154 of ICD-O) and morphology, date of diagnosis and type and date of treatment received.

Follow-up of all patients is regularly conducted by the Cancer Registry by interviewing the attending physician, and reviewing death certificates. For lost cases, a special effort was made for this study by reviewing medical records and pension files from the Social Security in order to improve quality of follow-up.

Survival was measured from diagnosis to 31 December 1988.

Three blood banks exist in Majorca and no other source of blood or blood products is operational on the island. Transfusion records were reviewed for the period 1982 to 1987, and included information on name, age, sex, blood product received (whole blood, packed red blood cells, plasma), number of units and date of transfusion(s).

Linkage of the blood banks and cancer registry files was carried out manually and confirmation of the transfusion prescription was verified by reviewing clinical records.

Definitions

Radical surgery: patients with macroscopic complete tumour removal by surgery.

Operative mortality: death within the 3-month period following diagnosis. The average delay in treatment following diagnosis was 1.5 months.

Perioperative transfusion: transfusion given between the 2-

month interval around the day of surgery; (three categories: pre, intra, postoperative).

Tumour topography: three categories: right colon (from caecum to hepatic flexure); left colon (tranverse colon, splenic flexure, descending and sigmoid colon); and rectum (rectum and rectosigma).

Other variables were coded in the following manner: sex, male/female; age, five categories, < 50, 50–59, 60–69, 70–79 and 80 + years; stage at diagnosis, three categories, Dukes A, Dukes B, Dukes C; blood product, two categories, red blood cells, total blood; number of units, two categories, 1–2, 3 or more.

Statistical methods

Differences of variable distribution between transfused and non-transfused patients were compared using the χ^2 test.

Survival for the entire series was calculated using the Kaplan and Meier method and the impact of each known prognostic factor on survival was first evaluated by stratifying the series according to the variable. The 95% confidence interval (CI) was calculated using Greenwood's method.

Multivariate analyses using Cox's model were also conducted to evaluate the role of each factor after adjustment for the effects of the remaining prognostic factors in the series. The analysis was first conducted for all patients undergoing radical surgery and repeated after excluding the cases included in the operative mortality category.

The size of our study was sufficient to detect with 95% confidence and power of 80% a difference in survival of 10% between the expected levels of survival for colorectal cancer patients (i.e. 75% survival rate for the non-transfused patients versus 65% among transfused) [16].

The Presta programme was used for univariate analysis, and Egret for the multivariate analysis.

RESULTS

Of the 1052 cases registered in the study period, 152 were excluded for the following reasons: 10 developed second neoplasms, 29 lacked information on the date of diagnosis and/or of treatment, 84 were not operated on and 29 received adjuvant treatment (chemotherapy and/or radiotherapy).

Of the remaining 900 cases treated exclusively by surgery (radical or palliative), 388 survived, 498 died and 14 were lost during the study period. The median follow-up was 42.6 months. 302 patients received palliative surgery and were not considered further. Of the 698 patients undergoing radical surgery, 76 (10.9%) died within 3 months of diagnosis. It was thought that this group, characterised by early death, represented a subset of cases in which poor prognosis was probably associated with the prescription of blood transfusion and with fatal surgical complications. When comparing these 76 patients with the total series (data not shown), the predominant variables strongly associated with poor prognosis were advanced age ($P < 0.0001$) and primary tumour in the right colon ($P < 0.02$). Advanced stage of disease and male sex were also more common in this group, but the differences were not statistically significant. Concerning number of transfusions, these patients received, on average, 5.2 units versus 3.5 for the entire group ($P = 0.001$). Because of the difficulties of interpreting the effects of blood transfusion on this high-risk group of patients, the conclusion of our study was based on the analysis that excluded these subjects.

Table 1 shows the breakdown by the key variables considered in the series of 686 cases entered into the study and the distribution in the series that had (348), and had not (338) received blood transfusions. 12 patients lacked information on transfusion and were excluded. Between transfused patients, 152 (43.68%) received red blood cells, 85 (24.43%) total blood, 5 (1.44%) plasma and 106 (30.46%) combinations of the above. Results were analysed in two categories: red blood cells (152 patients) and total blood (the rest of the patients). The number of units transfused per subject was as follows: 46 (13.22%) of patients received 1 unit, 104 (29.88%) received 2 units, 77 (22.13%) received 3 units, 46 (13.22%) received 4 units and 75 (21.55%) received 5 or more.

Table 2 shows the results of univariate analysis restricted to patients who survived more than three months after diagnosis. No significant differences were observed by transfusion status for age group, sex or topography of tumour in the bowel, but non-transfused patients with Dukes A and B stages had better survival than those who had received blood transfusion. In addition, no significant difference was found in survival between patients who received red blood cells and those who received total blood ($P = 0.25$). The association between number of units and survival was inconsistent.

After excluding the 76 patients previously defined as operative mortality, 28 patients with Dukes D stage and 27 for whom topography was poorly defined, a Cox's analysis was conducted including as regressor terms: age, sex, topography, stage and number of blood units received (Table 3). From this analysis, stage and topography were identified as prognostic variables, and after adjusting for these variables, blood transfusion was not associated with survival, the hazard ratio for transfused patients being 1.0 (95% CI 0.69–1.43) for those who received 1–2 units and 1.3 (95% CI 0.93–1.82) for recipients of more than 2 units. When the 76 patients who died prematurely were not excluded, the results were essentially the same. Figure 1 shows a representation of baseline survival which corresponds to all regression variables simultaneously taken on the value zero, for transfused and non-transfused patients computed with this model. For subjects receiving blood transfusion and their controls, the number of patients observed at 3 years was 112 and 120, and at 5 years 49 and 48, respectively. The corresponding adjusted survival at 3 years was 78.7 and 78.6 and at 5 years 63 and 69%.

DISCUSSION

The hypothesis under consideration is that blood transfusion might negatively influence survival of colorectal cancer patients through a poorly understood mechanism involving immunodepression. Any such effect should be observed in a long-term follow-up study of patients with a relatively long survival period. Blood transfusion is a major therapeutic resource for acute blood loss at the time of surgery or within the weeks around surgery, and it can be assumed that perioperative complications are associated with both blood transfusion and early death. Therefore a suitable group in which to test the immunodepression hypothesis are those patients who survive the perioperative period. However, in this group, we detected no effect of having received blood or blood products, nor of any dose response effect with the number of units received.

The key prognostic factors identified were, as expected, the stage of the disease according to the Dukes staging system, advanced age and rectal cancer as compared to any of the colonic tumours.

This evaluation has several advantages over previously published results. It is a large series with balanced number of recipients and non-recipients of blood transfusion products. It

Table 1. Description of the study population by transfusion and prognostic variables

	Total	Transfused	(%)	Not transfused	(%)	*P*
Number of cases	686	348	(50.7)	338	(49.3)	
Median survival (months)	48	40		63		
Mean follow-up time (months)	29	28.4		30.6		
Number of deaths	301	175	(58.1)	126	(41.9)	
Age groups (years)						
< 50	67	29	(43.3)	38	(56.7)	
50–59	106	51	(48.1)	55	(51.9)	
60–69	194	91	(46.9)	103	(53.1)	
70–79	243	129	(53.1)	114	(46.9)	
> 79	71	46	(64.8)	25	(35.2)	
Unknown	5	2	(40.0)	3	(60.0)	ns
Sex						
Male	374	186	(49.7)	188	(50.3)	
Female	312	162	(51.9)	150	(48.1)	ns
Topography						
Right colon	130	64	(49.2)	66	(50.8)	
Left colon	223	85	(38.1)	138	(61.9)	
Rectum	307	186	(60.6)	121	(39.4)	< 0.01
Multiple and unknown	26	13	(50.0)	13	(50.0)	
Stage						
Dukes A	116	51	(44.0)	65	(56.0)	
Dukes B	294	159	(54.1)	135	(45.9)	
Dukes C	214	106	(49.5)	108	(50.5)	
Metastasis	27	17	(63.0)	10	(37.0)	
Unknown	35	15	(42.9)	20	(57.1)	ns
Operative mortality	73	46	(63.0)	27	(37.0)	< 0.01
Number of units transfused						
1	46	(13.2)				
2	104	(29.9)				
3	77	(22.1)				
4	46	(13.2)				
5+	75	(21.6)				

ns, non-significant.

is population-based thus avoiding the selection bias that can occur in any hospital-based series. The follow-up of the cases is fairly complete, as is the ascertainment of the use of blood transfusion. The crude survival analysis stratified by age and sex identified blood transfusion as a prognostic factor, and individuals having received at least one blood transfusion showed a markedly lower survival time as compared to non-recipients (39 versus 53% at 62 months of follow-up, $P < 0.05$). Another risk factor identified in this analysis was the percentage of involved lymph nodes in patients with Dukes C stage. However, multivariate analysis using all the identified confounders showed that the observed transfusion effect was due to confounding by the stage and site of the primary tumour. The lower survival among the transfused group shown in Figure 1 after 36 months of follow-up was not statistically significant, and could be explained either as a true residual deleterious effect of blood transfusion or more likely by the limitations of the statistical adjustments that were made in the evaluation of survival. The latter usually results from using variables that inevitably convey misclassification (such as stage of the disease) or from ignoring relevant prognostic variables for survival, for which no information was available in this retrospective study. Examples of these are the magnitude of the surgical procedure, the concurrent effects of other treatments, concurrent diseases or the cause of death.

Among previously published studies on blood transfusion and prognosis in colorectal cancer [1–15, 17, 24], several had a number of cases greater than 200 [9–15, 17-24], and the analysis included other prognostic variables. In five of these studies, [10, 13, 14, 17, 18] similar methodology to ours was used (i.e. exclusion of postoperative deaths and adjustment for age, sex, stage and site of the primary within the colorectum). Of these, none identified blood transfusion or transfusion of any specific blood product as a risk factor, although the latter was evaluated in only two studies [14, 17].

In our data, after adjustment for the major prognostic factors, the differences in survival between the transfused and non-transfused groups varied from 0% at 36 months of follow-up to a maximum of 7% at 54 months. The average differences in survival time between the two groups were of the order of 1%. Under these conditions, to detect a difference that would be statistically significant at the 5% level with power of 80%, the study size would need to be almost double the number we had (693 transfused and 693 non-transfused patients) [16]. Therefore, although our study is among those with a large number of cases, it still suffers from some size limitations. However, the clinical and biological relevance of a statistically significant difference at such low level remains a matter of opinion.

Immunodepression has been clearly demonstrated to be a risk

Table 2. Five-year survival and median survival time in colorectal cancer patients undergoing radical surgery and who survived at least 3 months from diagnosis

	Transfused		Not transfused		
	% 5-year survival	Median survival (months)	% 5-year survival	Median survival (months)	P^*
Age group (years)					
< 50	x	46	x	> 40	0.26
50–59	55	73	70	63	0.22
60–69	50	60	50	60	0.53
70–79	41	45	52	71	0.59
> 79	0	34	x	48	0.22
Sex					
Male	41	44	50	60	0.07
Female	46	46	63	71	0.07
Topography					
Right colon	46	53	x	31	0.65
Left colon	56	62	64	71	0.14
Rectum	36	41	43	57	0.55
Stage					
Dukes A	55	68	68	> 60	0.04
Dukes B	52	62	65	> 71	0.01
Dukes C	28	40	38	31	0.72
Blood product					
Red blood cells	34	41	—	—	
Total blood	38	37	—	—	0.25
Number of units transfused					
0	—	—	54	63	—
1	58	> 60	—	—	—
2	30	38	—	—	—
3	57	> 65	—	—	—
4	36	22	—	—	—
> 4	x	38	—	—	—

*Significance of the log-rank test between transfused/not transfused groups. x = not estimable for short follow-up period in those groups.

factor for tumour development in humans [25], but the evidence is limited to individuals having received high doses of immunosuppressants for long periods of time. The best evidence is from registries of patients undergoing renal (or other organ) transplants. In these patients, excess of liver cancer, lymphomas etc., have been reported in a 25-year follow-up study [26]. No excess of colorectal cancer was observed in these series [26, 27]. In our study, we could not identify any effect of transfusing red blood cells or total blood. The limited number of subjects receiving only plasma or other blood products precluded any separate analysis.

Animal experiments have shown that transfusions were associated with improved allograft survival among immunodepressed animals, but transfusion had no effect on graft survival in the absence of immunosuppression. This effect was usually observed when transfusion was administered preoperatively [28]. Differences in tumour growth of transplanted tumours in relation to blood transfusion have been occasionally described depending upon the species, tumour, route of inoculation and time of transfusion (pre- or post-tumour inoculation) [29].

Studies based on humans receiving blood products or total blood, who have been monitored for markers of immunosuppression, indicate that various suppressor cell populations are activated following transfusion, such as cytotoxic lymphocyte precursors [30] and natural killer cells [31–33]. These effects have been observed between 1 or 2 months following transfusion. However, similar immunosuppressive effects have been described after surgery without transfusion and have been attributed to surgical procedure [34] or anaesthesis [35]. A recent prospective study, which compared the use of autologous blood with allogenic blood in colorectal cancer patients treated surgically did not find differences between these types of transfusions [36].

CONCLUSION

Our data does not support the hypothesis that perioperative blood transfusion adversely affects long-term survival of colorectal cancer patients undergoing radical surgery. The apparent deleterious effect of blood transfusion previously reported by other studies may be explained, to a large extent, by the effect of other powerful prognostic factors, notably stage of the disease and site of the primary. More refined estimates of the effects, if any, of blood transfusion would require studies much larger in size than the present one and which, in addition, should also consider other prognostic variables difficult to obtain in retrospective assessments. Given the limited evidence produced by animal experiments and the intensity of the immunosuppression required to observe any significant excess of tumour progression in humans, we conclude that it is unlikely that any adverse effect of blood transfusion on survival exists.

Table 3. Prognostic values of selected factors among colorectal cancer patients treated by radical surgery and who survived at least 3 months from diagnosis

	Hazard ratio	95% CI	*P*
Stage			
Dukes A	1		
Dukes B	1.53	0.94–2.50	< 0.001
Dukes C	3.57	2.22–5.75	
Topography			
Right colon	1		
Left colon	0.96	0.61–1.52	
Rectum	1.87	1.22–2.86	< 0.001
Age (years)			
< 50	1		
50–59	0.61	0.33–1.12	
60–69	0.80	0.46–1.38	
70–79	0.88	0.51–1.50	
80 +	1.30	0.68–2.44	0.12
Sex			
Males	1		
Females	0.83	0.61–1.11	0.21
Number of units transfused			
0	1	–	
1–2 units	1	0.69–1.43	
> 2 units	1.30	0.93–1.82	0.22
Ever transfused	1.16	0.87–1.55	0.32

Cox model adjusted for all variables in the table using 536 valid observations.

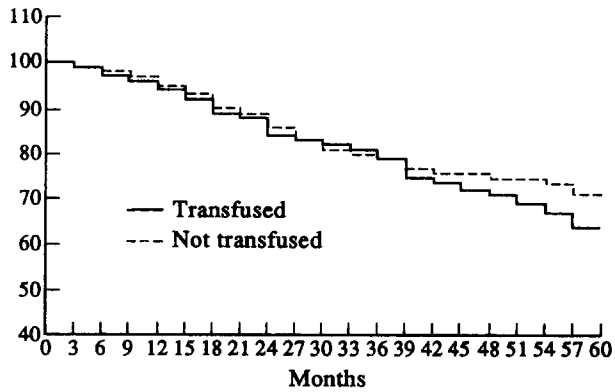

Figure 1. Survival of 536 patients with colorectal cancer treated by radical surgery and who survived at least 3 months from diagnosis by exposure to blood transfusion. (Cox model adjusted for age, sex, stage and tumour topography as defined in the text.)

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Clinical Prediction of Survival is More Accurate Than the Karnofsky Performance Status in Estimating Life Span of Terminally Ill Cancer Patients

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Predicting the survival of terminally ill cancer patients can help in informing patients and their families, in programming therapy and assistance models, and in utilising existing resources correctly. Clinical prediction of survival (CPS) and Karnofsky performance status (KPS) are two factors which have already been described in the literature. The aim of our study was to verify their respective predictive value with regard to actual survival. In our study of 100 consecutive patients, the CPS obtained a higher prediction accuracy than that reported previously (correlation coefficient with actual survival = 0.51) and than that obtained with KPS alone (correlation coefficient = 0.37). The median difference between predicted and expected survival was only 1 week. The resultant predictivity could be further improved by integrating other prognostic factors studied in larger prospective, multicentric studies.

Key words: prognostic factors, terminal cancer patients, palliative care
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INTRODUCTION

Many biological and clinical features have been shown to be useful as predictive factors of survival in cancer patients at initial diagnosis and at the first finding of metastatic disease. Estimation of life span is, however, much more problematic in far advanced and terminally ill cancer patients. An accurate prediction of life expectancy would enable us to carry out an accurate decision-making and planning of terminal care with regard to therapeutic