

National Study of Subarachnoid Haemorrhage

FINAL REPORT of an audit carried out in 34 Neurosurgical Units in the UK and Ireland between 14 September 2001 to 13 September 2002

FEBRUARY 2006

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National Study of Subarachnoid Haemorrhage

FINAL REPORT of an audit carried out in 34 Neurosurgical Units in the UK and Ireland between 14 September 2001 to 13 September 2002

On behalf of: Society British of Neurological Surgeons The British Society of Neuroradiologists Clinical Effectiveness Unit, The Royal College of Surgeons of England Published by The Royal College of Surgeons of England Registered Charity No. 212808

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Contents

Ackn	owledgements	vi	7.	Risk factors associated with unfavourable outcome	
Execu	utive Summary	vii		(death and disability)	21
	•		7.1	Patient characteristics	21
Reco	mmendations	ix	7.2	Management of patients	21
1.	Introduction	1	8.	Variation by Neurosurgical Unit	25
1.1	Background to the study	1	8.1	Patient characteristics	25
1.2	Subarachnoid haemorrhage	1	8.2	Management of patients	26
1.3	The aims of the National Study of		8.3	Outcomes	28
	Subarachnoid haemorrhage	2	8.4	Multilevel model for comparison of outcomes between NSUs	31
2.	Study methods	3	8.5	Conclusions	31
2.1	Study organisation and design	3			J-
2.2	Patient selection and recruitment	3	Refe	rences	32
2.3	Clinical data collection	3			
2.4	Definitions for data collection and analysis	,	APPEI	NDIX 1 Abbreviations and glossary	
	of data	6		of terms	33
2.5	Data quality	9			
2.6	Data analysis	9	APPEI	NDIX 2 Clinical data collection form	36
3.	Description of all patients recruited to the study	10	APPEI	NDIX 3 Follow up questionnaire and patient consent form	42
4.	Characteristics of patients with confirmed ruptured aneurysms	12			
5.	Management of patients with confirmed ruptured aneurysms	15			
6.	Outcomes for patients with confirmed ruptured aneurysms	18			

Tables		
Table 3-1:	Characteristics of the 3174 patients included in the study	10
Table 4-1:	Admission characteristics of the 2,397 patients with confirmed ruptured aneurysms and no coexisting	
	neurological pathology, by mode of treatment	13
Table 4-2:	Site of ruptured aneurysms	14
Table 5-1:	Time to admission to NSU, treatment and discharge by mode of treatment	16
Table 5-2:	Proportion of patients coiled and clipped before and after ISAT ceased recruitment	17
Table 6-1:	Pre-repair deterioration by mode of treatment in all patients	18
Table 6-2:	Post-repair deterioration by mode of treatment in all patients repaired	19
Table 6-3:	Length of stay, in days, by mode of treatment	19
Table 6-4:	Patient outcome in hospital and at six months	20
Table 7-1:	Outcomes in 1969 repaired patients, for whom outcome was available according to patient	
	characteristics (univariate analysis)	22
Table 7-2:	Full risk assessment model (multivariate logistic regression)	23
Table 7-3:	Outcomes in 1969 patients, who received a repair procedure (clip or coil) and for whom outcome	
	was available	24
Table 8-1:	Variation of patient characteristics by NSU of 2397 patients with confirmed aneurysms and no	
	coexisting pathology repaired or not repaired (n % indicates the overall proportion of patients,	
	percentile and range indicate the variation between NSUs)	27
Table 8-2:	Variation of patient management, by NSU in 2,397 patients with confirmed aneurysms and no	
	coexisting pathology (n % indicates the overall proportion of patients, percentile and range	
	indicate the variation between NSUs)	28
Table 8-3:	Variation of patient outcome by NSU of 2,397 patients with confirmed aneurysms and no coexisting	
	pathology repaired or not repaired (n % indicates the overall proportion of patients, percentile and range	
	indicate the variation between NSUs)	28
Figures		
Figure 1:	Flow Diagram of eligibility for inclusion of patients into the National Study of SAH	4
Figure 2:	Patient flow diagram of study for the first year of data collection	5
Figure 3:	Number of patients recruited in the first year of data collection, by month of ictus	11
Figure 4:	Time from ictus to treatment in days for patients clipped and coiled (curtailed at 20 days)	15
Figure 5:	Proportion of patients coiled each month in ISAT and non ISAT centres (coiling centres only),	
	by month of surgery	17
Figure 6:	Number of patients recruited to the study in the first year, by NSU	25
Figure 7:	Proportion of low risk* patients (n = 875 out of $2,397$ patients with confirmed aneurysms)	26
Figure 8:	Proportion of patients clipped or coiled out of all patients in the NSU with confirmed aneurysms (n=2,397)	27
Figure 9:	The median time from ictus to procedure by NSU (shows median and 25th and 75th percentiles) –	
	all repaired patients	29
Figure 10:	Unadjusted unfavourable outcome rates in 34 NSUs for all repaired patients (clip or coil) (n=1,969)	
	by NSU (in order of repaired patients). (Vertical lines represent 95% confidence intervals)	29
Figure 11:	Unadjusted Odds Ratios and 95% confidence intervals in 34 NSUs for all repaired patients	
	(clip or coil) (n=1,969) by NSU (in order of number of repaired patients)	30
Figure 12:	Adjusted Odds Ratios and 95% confidence intervals in 34 NSUs for all repaired patients	
	(clip or coil) (n=1969) by NSU (in order of sample size)	30

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Foreword

In 2001, the Society of British Neurological Surgeons and Royal College of Surgeons of England initiated an audit of subarachnoid haemorrhage patients managed in Neurosurgical Units (NSUs) across the UK and Ireland. All neurosurgeons were invited to take part. The main objective of the study was to develop an outcome indicator that could subsequently be used for a national comparative audit of NSUs.

Funding was obtained from the Department of Health through the Clinical Outcomes Project of the Academy of Medical Royal Colleges. Data were collected on SAH patients from all 34 NSUs and a national database was developed including information on patient outcome at six month after discharge. These data provided us with a unique opportunity to describe the variation in patient characteristics, management and outcome in all NSUs in the UK and Ireland. There has previously been no other national research that compared the performance of NSUs in the UK and Ireland.

This is the final report of the National Study of Subarachnoid Haemorrhage. This report specifically covers the collection and analysis of data on patients with a confirmed subarachnoid haemorrhage who were admitted between the 14th September 2001 and 13th September 2002 to one of the 34 neurosurgical units (NSUs) in the UK and Ireland.

This study was carried out by the Society of British
Neurological Surgeons and the Clinical Effectiveness Unit
of The Royal College of Surgeons of England and The London
School of Hygiene and Tropical Medicine. The combination
of academic staff, consultant neurosurgeons and
neuro-radiologists ensured the methodological and clinical
robustness of the study. The study would not have been
possible without the good will and hard work of the
participating NSUs. They collected the data, helped with
the data validation, and follow patients up for six months.

We would like to thank everyone for their co-operation and contribution

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The study was carried out by the Clinical Effectiveness Unit of The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine in association with The Society of British Neurological Surgeons.

The Department of Health provided initial funding through the Clinical Outcomes Project of the Academy of Medical Royal Colleges. The Clinical Effectiveness Unit of The Royal College of Surgeons of England further supported the study. Julia Langham (Project Coordinator) received an MRC Training Fellowship in Health of the Public and Health Services Research.

The Steering Group

The Steering Group consisted of representatives the Society of British Neurological Surgeons (SBNS), The British Society of Neuroradiologists (BSNR) and academic staff from the Clinical Effectiveness Unit (CEU) of The Royal College of Surgeons of England and London School of Hygiene and Tropical Medicine

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The Project Team and Steering Group had overall responsibility for the study. Mr Ken Lindsay and Dr Barnaby Reeves were responsible for initiating the study. The Steering Group was responsible for developing the protocol and audit. Julia Langham coordinated the study, supported by Lynn Copley and Jackie Horrocks. The statistical analyses were carried out by Julia Langham, supported by Dr Reeves, Dr van der Meulen, and Dr Browne. Additional statistical support was given by Dr James Lewsey, Lecturer in Medical Statistics (CEU), Dr David Cromwell, Lecturer in Health Services Research (CEU) and Carl Gibbons, Research Fellow (LSHTM). Julia Langham wrote the report supported by the Steering Group and Project Team.

Executive Summary

Executive Summary

The National Study of Subarachnoid Haemorrhage collected information on patients who had a subarachnoid haemorrhage (SAH) and were admitted to a neurosurgical unit (NSU) in the UK and Ireland between 14 September 2001 and 13 September 2002. The aims of the study were to describe the characteristics of patients, the care given to them in an NSU and their outcome at six months, as well as to investigate the factors that influenced their outcomes.

Background

SAH is a type of haemorrhagic stroke caused by bleeding into the subarachnoid space around the brain. The incidence of SAH in the UK is approximately 8 per 100,000 population. SAH is most often caused by a rupture of a cerebral aneurysm (70%). Arteriovenous malformations are another relatively frequent cause of SAH (10%). A traumatic head injury can also lead to SAH. In most of the remaining patients, the cause of SAH is unknown. All patients with SAH, except those with a traumatic head injury, were eligible for inclusion in this study. Only patients with a confirmed aneurysm form the focus of this study. Patients in whom the SAH had a different aetiology or those in whom an aneurysm could not be confirmed were excluded from the analyses.

Patients included in the study

All 34 NSUs in the UK and Ireland participated in the study and 3,174 patients were included. Of these patients, 2,397 (76%) had a confirmed aneurysm and 59 (2%) had an arteriovenous malformation. No aneurysm was identified in a further 718 (23%) patients, because of a negative angiography in 486 (15%) patients, and because no angiography was undertaken due to early death or a poor physical condition in 232 (8%) patients.

Characteristics of patients with confirmed aneurysms
The median age of the 2,397 patients with a confirmed
aneurysm was 52 years. 66% of the patients were women.

A large proportion of the patients (79%) were in good neurological condition at admission (World Federation of Neurological Surgeons grade I or II). CT scans demonstrated only a small amount (or no blood) in the subarachnoid space in 37% of patients and a large amount in 31%. The majority of aneurysms (70%) were less than 10mm in diameter and 89% of the aneurysms were located in the anterior circulation. Almost half of the patients (44%) had concurrent medical conditions such as hypertension (22%) or ischaemic heart disease (6%).

Mode and timing of repair procedure

Of the 2,397 patients, active repair was attempted in 2,198 patients with a confirmed aneurysm (92%): 1,269 were treated by surgical clipping (53%); 905 by endovascular coiling (38%); a further 24 patients underwent another type of repair (1%); and 199 patients received no repair (8%).

The proportion of patients who underwent coiling increased over the study period. This increase was thought to be the result of the dissemination of results from the International Subarachnoid Aneurysm Trial (ISAT). ISAT is a multicentre randomised trial that compared the efficacy and safety of endovascular coiling with surgical clipping in SAH patients. Recruitment to ISAT stopped early after a planned interim analysis that showed an absolute difference of 7% in the proportion of patients who were dependent or dead 1 year after SAH in favour of coiling (24% of coiled and 31% of clipped patients). In our study, the proportion of patients coiled increased with 17% from 37% of the 1752 patients treated before ISAT stopped recruitment (May 2002) to 53% of the 645 patients who were treated after ISAT stopped recruitment.

Of the 2,198 patients who underwent a repair procedure, 32% were treated within 2 days of the haemorrhage, a further 39% between 3 and 7 days and 10% between 8 to 10 days. Patients who were treated with coiling were discharged

earlier than patients who were treated with clipping (median length of stay 15 days and 18 days, respectively).

In 528 of the 2,397 patients with a confirmed aneurysm (22%), the neurological condition deteriorated before any repair was carried out. Deterioration delayed the repair procedure in 188 (8%) and prevented the procedure in 130 (5%). Of the 2198 patients who underwent a repair, 711 (32%) deteriorated after the procedure. This was the result of cerebral ischaemia in 485 patients (22%). Patients who underwent clipping were more likely to suffer cerebral ischaemia than patients who underwent coiling (25% and 19%, respectively). Hydrocephalus caused deterioration after repair in 141 (6%), but the frequency of hydrocephalus did not differ between patients who were clipped or coiled. Re-bleeding occurred in 44 (2%) of the 2,198 patients who underwent a repair, more commonly in coiled patients than in those clipped (3% and1%, respectively).

Hospital and six-month outcome

Of 2,397 patients with a confirmed aneurysm, 2,125 (89%) patients were discharged from the NSU alive. Of the survivors, 984 (47%) were discharged home, 960 (45%) went back to the referring hospital, and 170 (8%) were admitted to a rehabilitation centre.

At six months, all 2,397 patients were followed up to assess functional outcome. Outcome was defined as unfavourable if the patient was severely disabled (dependent) or had died. Overall, 829 patients with a confirmed aneurysm had an unfavourable outcome (38%). There was no significant difference in the unfavourable outcome at six months in patients treated with clipping (35%) or coiling (34%).

There were no statistically significant differences in the proportion of patients with an unfavourable outcome across the 34 participating NSUs when case-mix differences and the multilevel nature of the data were taken into account.

Risk factors

In the 2,174 patients treated by either clipping or coiling, risk factors associated with an unfavourable outcome were higher age, poorer neurological condition on admission, a larger amount of blood in the subarachnoid space on CT scan, aneurysm diameter greater than 10mm and sited on the posterior circulation, and the presence of any comorbid condition such as hypertension and ischaemic heart disease.

Recommendations

- Where coiling facilities or expertise are not available, clipping of aneurysms is an acceptable alternative on current evidence
- With the change in practice witnessed in this study towards coiling, it is important to audit practice and to assess long term outcome
- Any future audit of practice and assessment of outcome should include the risk factors for an unfavourable outcome identified in this study (age, neurological condition on admission, blood in the subarachnoid space on CT, size and site of aneurysm, and presence of comorbid conditions such as hypertension)
- Outcome measures should include mortality and complications (such as re-bleeding and re-admissions) as a minimum in any audit of SAH patients, although an additional measure of functional status at 6-12 months is recommended.

1 Introduction

1.1 Background to the study

The consultation document, A First Class Service¹ demonstrated the Governments' intention to use the results of comparative audit to underpin clinical governance. At the same time, the Government acknowledged that comparisons between surgeons, units or hospitals will not be meaningful unless they are based on unbiased and valid measures of outcome and have been adjusted as far as possible for variations in case mix.

In this report, we describe the results of a study that was set up to develop an indicator that could subsequently be used for a national comparative audit of neurosurgeons in the UK and Ireland. Initial funding was received from the Department of Health through the Clinical Outcomes Project of the Academy of Medical Royal Colleges (June 2000). There has previously been no other national research comparing performance of UK neurosurgical units (NSUs).

1.2 Subarachnoid haemorrhage

Subarachnoid haemorrhage (SAH) is a type of haemorrhagic stroke caused by bleeding in the subarachnoid space around the brain. The incidence of SAH in the UK is approximately 8 per 100,000 population.²

In most patients, the haemorrhage is caused by a cerebral (intracranial) aneurysm. Aneurysms develop at the site of a defect in the wall of the intracranial blood vessels. The weakened wall balloons out to form a blood filled sac, known as a saccular aneurysm. This is unstable and may rupture causing haemorrhage into and around brain structures. In about 10% of patients the haemorrhage is caused by an arteriovenous malformation (AVM), a condition where blood vessels cluster together and form abnormal connections that are weak and prone to bleeding. In another 10% investigation reveals no evident vascular abnormality and the aetiology remains unknown. Head trauma may also cause blood vessels to rupture within the brain. This study

is concerned only with spontaneous aneurysmal SAH, and does not include haemorrhage caused by head injury.

The aetiology of aneurysm formation is uncertain, although there is likely to be a genetic component (congenital predisposition). A number of other risk factors such as smoking, hypertension and alcohol abuse may contribute.

SAH represents less than 5% of all strokes. However, it is a serious condition associated with a poor prognosis. It is estimated that up to 50% of patients suffering an aneurysmal SAH will either die or be left with serious disability. Without treatment approximately 25-30% of patients would re-bleed within the first four weeks from the haemorrhage. Of these, approximately 70% would die. 6

It is estimated that there are approximately 4800 cases of SAH in the UK per year. Approximately 15% of SAH cases die before they are admitted to hospital. Of those that are admitted to hospital, approximately 5-10% are not admitted to a NSU (usually due to poor health or death). On the basis of these assumptions, about 3,800 SAH patients per annum are expected to be admitted to NSUs in the UK.

Clinical features of SAH include severe headache of sudden onset and neck stiffness, often combined with impaired conscious level and sometimes hemiparesis, impaired speech and/or seizures. Where SAH is suspected, a computed tomographic (CT) scan should confirm the diagnosis. The amount of blood on the CT scan reflects the severity of the bleed. However CT is not 100% sensitive and a few patients require lumbar puncture to confirm the diagnosis. The presence of an aneurysm is identified by either CT angiography or a cerebral angiogram. Angiography provides information about the size, shape and location of the aneurysm as well as the presence of vasospasm.

Treatment of SAH entails occlusion of the aneurysm by either surgical clipping or endovascular coilings to prevent re-bleeding. The surgical approach, involves a craniotomy (opening a flap in the skull), locating and dissecting out the aneurysm neck and occluding this with a clip. With the endovascular method of repair, coil embolisation, a catheter is inserted into a blood vessel in the patient's groin and guided up within the blood vessels to the aneurysm fundus. Platinum coils are then packed into the fundus through the catheter, until the aneurysm is obliterated.

Although coiling is becoming more common place, its uptake varies between NSUs and countries. This diversity of practice highlights the need to understand the relationships between the clinical characteristics of patients (ie case mix) and variations in management practice in order to interpret measures of outcome across NSUs.

Until recently, evidence for the effectiveness of coiling over clipping was not available. However the International Subarachnoid Aneurysm Trial (ISAT), a large, multicentre prospective randomised trial compared the efficacy and safety of endovascular coiling with surgical clipping in SAH patients. ISAT recruited between 1997 to 2002. In May 2002, recruitment was stopped early by the Trial Steering Committee after a planned interim analysis showed an absolute difference of approximately 7% in the proportion of patients who were dependent or dead one year after the haemorrhage (coil 24% and clipping 31%).

1.3 The aims of the National Study of Subarachnoid haemorrhage

The National Study of SAH was initiated in all NSUs in the UK and Ireland in 2001. The overall aim was to describe the characteristics of patients with SAH and describe the management patients received and their outcomes as well as investigate the factors that influenced this outcome.

Specific objectives of the study were:

- To develop a minimum dataset to capture information on patient characteristics, management and outcome of patients with SAH
- To collect these data prospectively over a period of 12 months
- To describe characteristics of patients
- To describe the management of patients
- To describe the outcomes of patients
- To investigate the risk factors associated with outcome
- To develop a case-mix adjustment model, to allow comparison between different patient groups and across NSUs
- To describe variation across NSUs of patient characteristics, management and outcome

3

2 Study methods

2.1 Study organisation and design

The National Study of SAH was set up as a prospective study of patients with SAH, consecutively admitted to NSUs. All 34 NSUs in UK and Ireland participated. Data collection began on 14th September 2001. The data collected in the first 12 months of the study are described in this report. The study was a collaboration between the Society of British Neurological Surgeons (SBNS) and the Clinical Effectiveness Unit of The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine (CEU). The study was administered centrally from the CEU and was overseen by a Steering Group which included representatives of the SBNS, The British Society of Neuroradiologists and the CEU.

Based on estimates of incidence, estimates of the proportion of patients admitted to NSU with suspected SAH, and a survey of the number of patients who received surgical clipping, over 2,000 patients were expected to receive active treatment for SAH in NSUs in a period of one year. A cohort of this size was considered to have sufficient power to produce clinically meaningful results. It could be calculated that a cohort of this size would have a power of 95% to detect at a significance level of 5% anincrease in the risk of mortality from 10% to 15% associated with a risk factor present in 25% of the patients.

2.2 Patient selection and recruitment

The Steering Group identified a key contact in all NSUs. A letter was sent to these individuals to invite them and other staff members in their unit involved in the care of SAH patients to participate in the study. Recruitment of patients started on the 14th September 2001. Consultants were asked to recruit all patients who were suspected of having SAH caused by a ruptured cerebral aneurysm. Inclusion and exclusion criteria are shown in Box 2-1 below. A flow diagram explaining eligibility is shown in Figure 1.

Only the primary admission to the NSU where the patient was treated were included in the analysis, regardless of whether the patient was referred from another hospital. Consequently, NSUs who referred patients to other NSUs for coiling will be described in this report as having fewer cases than they may have originally admitted.

2.3 Clinical data collection

It was decided not to seek explicit written informed consent from patients for the clinical data collection for two reasons. First, many patients with SAH have a period of impaired consciousness which makes it inappropriate to obtain consent from the patients themselves. Second, the Steering Group expected that the obligation to obtain written consent might introduce selection bias as more severely ill patients would be less likely to be included. It was therefore

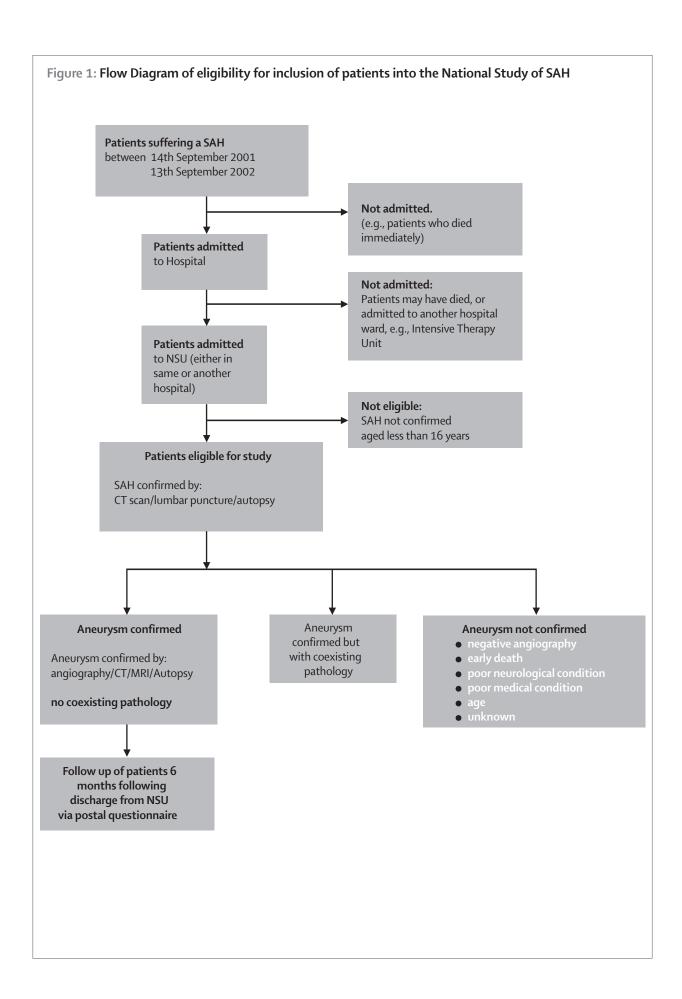
Box 2-1: Inclusion and exclusion criteria for patients eligible for inclusion

Inclusion criteria

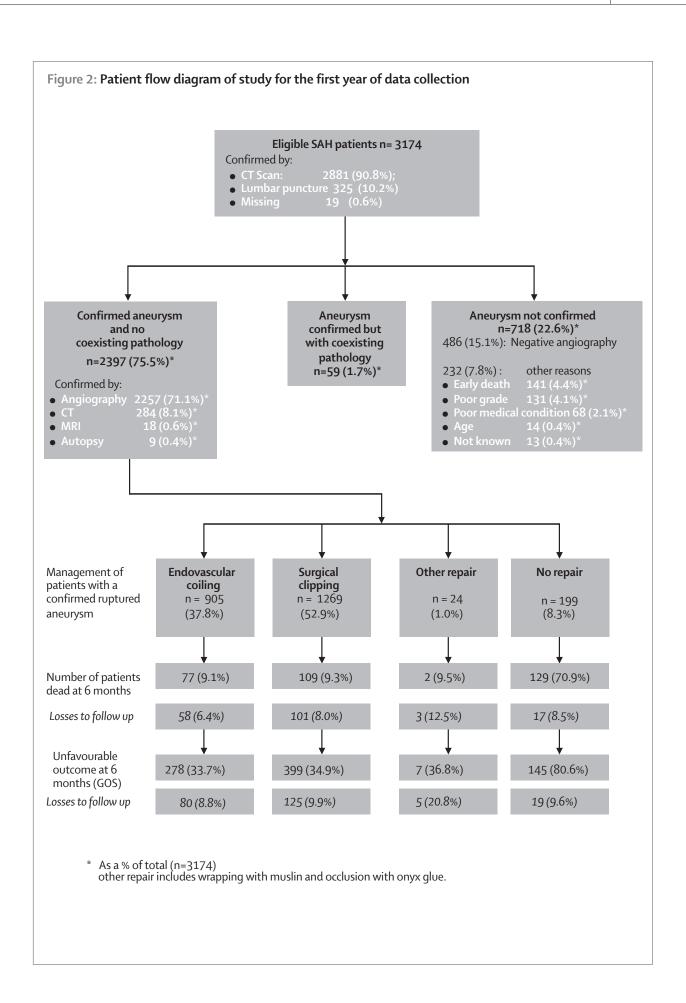
Patients with a SAH confirmed by a CT scan, lumbar puncture, or an autopsy with an ictus date (date of haemorrhage) between14 September 2001 and 13 September 2002, admitted to a NSU in the UK and Ireland.

Exclusion Criteria

Patients with traumatic SAH (i.e., SAH caused by head injury) rather than spontaneous SAH Patients less than 16 years old



5



agreed with the Multi Centre Research Ethics Committee (MREC) that consent would not be required if only anonymised data were transferred to the coordinating centre. Written informed consent was sought only at follow-up.

Consultant neurosurgeons were responsible for completing the clinical data form for each eligible patient under their care. These forms had to be completed as soon as possible after treatment. Once forms were completed and signed by the consultant neurosurgeon, they were sent to the coordinating centre. Each patient was assigned a unique identifier centre. The patient's hospital number was stored in a separate database and only used to allow linkage with the original clinical data for queries about data accuracy and the collection of follow-up data.

Box 2-2 summarises the data collected by neurosurgeons. The data collection form is shown in Appendix 2. Where an aneurysm could not be confirmed, a limited amount of data were collected.

2.4 Definitions for data collection and analysis of data

Patient characteristics

The neurological condition on admission was measured with the Glasgow Coma Scale (GCS)⁷. The GCS is a 15-point scale used to estimate the level of consciousness. There are three components, listed in Box 2-3 below. Scores for each component are added to obtain a 'coma score'.

Box 2-2: Summary of data collection

Data collected for all patients

Data collected for all patients

Additional data collected for patients with a confirmed aneurysm (and no coexisting pathology)

Core demographic and eligibility data

- Confirmation of SAH (with a CT scan, lumbar puncture or autopsy).
- Date of haemorrhage; date of admission, age

Risk factors

- Neurological deficit on admission (Glasgow Coma Score) and presence or absence of a motor deficit
- Pre-existing conditions (e.g., hypertension)

Confirmation of aneurysm

- Confirmation of aneurysm by angiography, CT or MR angiography or an autopsy
- Presence/absence of coexisting neurological pathology (e.g., AVM)

If an aneurysm could not be confirmed, or coexisting neurological pathology was detected no more data required

Additional data collected for patients with a confirmed aneurysm (and no coexisting pathology)

Further information on risk factors

- Size and location of the aneurysm.
- The amount of blood detected on the CT scan

Management of patients

Details of repair, i.e., Coiling, clipping, other (such as wrapping with muslin or gluing the aneurysm with onyx glue), or no repair received

Hospital outcomes

- Pre-repair or post-repair deterioration during the hospital episode;
- Hospital mortality
- Destination of discharge from NSU

Six month outcomes

 Glasgow Outcome Score was collected for patients at six months post discharge

Eye Opening Response	Opens spontaneously	4 points
, , , , , ,	Opens to verbal command	3 points
	Opens to pain	2 points
	None	1 point
Verbal Response	Oriented	5 points
	Confused	4 points
	Inappropriate words	3 points
	Incomprehensible speech	2 points
	None	1 point
Motor Response	Obeys commands	6 points
	localising to pain	5 points
	Flexion to pain	4 points
	Abnormal (spastic) flexion	3 points
	Extension to pain	2 points
	None	1 point

For the purposes of reporting and analysis of the data, the GCS was dichotomised as a Good or Poor clinical condition. A combination of the GCS and the presence or absence of a motor deficit was used to dewtermine the grade on admission as defined by the World Federation of Neurological Surgeons grading system (Box 2-4).

The site of an aneurysm was collected and then dichotomised for the purposes of analysis as either posterior circulation aneurysm or anterior circulation aneurysms as shown in Box 2-5 opposite.

Management of patients

The management of patients was recorded on the data collection form as coiled, clipped, other or no repair. In this report, patients are described according to the first procedure they received. For example, a patient would be classified as 'clipped' if they underwent clipping first but due to the failure of that repair procedure underwent a coiling afterwards to achieve occlusion.

Outcomes

Hospital outcomes

Pre-repair and post-repair deterioration was recorded for all patients with a confirmed ruptured aneurysm and no

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Definition	GCS	Motor deficit	WFNS Grade	Neurological condition on admission
Normal	15	Absent	1	Cood grade
†	13-14	Absent	II	Good grade
	13-14	Present	III	
. ↓	7-12	Absent or present	IV	Poor Grade
Unresponsive	3-6	Absent or/present	V	

Definition of site (as recorded on data collection form)	Category of aneurysm site
Anterior cerebral artery	
Anterior communicating artery or pericallosal	
Internal carotid artery	
Posterior communicating, bifurcation, ophthalmic or other internal carotid	Anterior circulation aneurysm
Middle cerebral artery	
Proximal or bifurcation	
Superior cerebellar; posterior cerebellar, posterior inferior cerebellar artery	Posterior circulation aneurysm
(PICA), basilar bifurcation, other	

coexisting neurological pathology. Pre-repair deterioration was defined as a reduction of the GCS (of 1 point on the motor score or 2 points on the verbal score). Post repair deterioration was defined as either a reduction of the GCS as above, or whether the patient was transferred back to a high dependency or intensive therapy unit or had a delayed discharge from the HDU/ITU due to deterioration.

Destination at discharge was recorded as being discharged home, to the referring hospital or to a rehabilitation unit. In hospital mortality was also recorded.

Patient outcomes at six months

All patients with a confirmed ruptured aneurysm and no coexisting neurological pathology were eligible to be

GOSE score	Performance level	Dichotomous outcome
1	Upper good recovery	
	Good recovery	
2	Lower good recovery	
	Good recovery with minor social or mental deficits	Favourable outcome
3	Upper moderate disability	ravourable outcome
	Able to return to work at reduced capacity, reduced participation in social activities	
4	Lower moderate disability	
	Unable to return to work or participate in social activities	
5	Upper severe disability	
	Dependent on others for some activities	
6	Lower severe disability	
	Completely dependent on others	Unfavourable outcome
7	Severely disabled	Offiavoorable outcome
	Either pre-haemorrhage or for some other reason not related to the haemorrhage.	
8	Dead	

9

contacted at 6 months. Follow-up packs for each patient included a cover letter, questionnaire, and consent form. These were sent from the CEU to the NSU where the patient had been treated. After checking that the patient had not died since discharge, the NSU forwarded the pack to the home address of the patient held at the hospital. The questionnaire, completed by the patient or the patient's carer, used the Extended 8-point Glasgow Outcome *Score* (GOSE)⁹ to measure a patient's ability to carry out activities of daily living following the haemorrhage, compared to before the haemorrhage. A copy of the consent form and follow-up questionnaire can be found in the Appendix 3.

Data from the questionnaire was used to calculate the 8-point GOSE. The GOSE was then dichotomised for purposes of this report as either a favourable outcome (good recovery or moderate disability) or an unfavourable outcome (severe disability or death). This is shown in Box 2-6 below.

If no response was received from the patient after one month, a reminder letter was sent. If there was no response to the questionnaire or the reminder letter, the NSU was asked to check whether they had been notified about the patient's death and whether the address was correct.

2.5 Data quality

In the year following the first year of data collection, a number of data quality checks were made by CEU staff. NSUs were visited to establish completeness of inclusion of the eligible SAH patients.

Ascertainment of eligible patients: During these visits, possibly eligible patients were identified from theatre logs; angiographic coiling logs; lists kept by neurosurgical staff of SAH patients and, in some cases, patient administration systems (PAS data). Where possibly eligible patients were identified that had not been included in the database, the NSU were asked to verify eligibility, and if the patient was found to be eligible, the NSU was encouraged to collect data retrospectively in order to attain full ascertainment.

Missing and inconsistent data: The quality of the data was checked first by using computerised checks for missing and inconsistent data. Reports of queried data were sent to NSUs throughout the data collection period for verification. Data were updated when queries were answered.

Validation of 10% of case notes: CEU staff also validated a sample of 10% of case notes from each NSU. Information about the methods used to assess the data quality and the results of the exercise are available from the CEU on request.

2.6 Data analysis

Logistic regression was used to assess the association between patient risk factors and outcome.10 Stata software (Release 8) was used for all statistical calculations (www.stata.com). Multi-level multivariate analysis was used to adjust for potential confounding factors (age, neurological condition on admission, site and size of aneurysm, the amount of blood found on the CT scan, and pre-existing conditions such as heart disease or hypertension), and to account for the clustering of patients within NSUs. Multilevel analysis was performed with MLwiN software (www.ioe.ac.uk/mlwin). All p-values are 2-sided, and p-values lower than 0.05 are considered to indicate a statistically significant result.

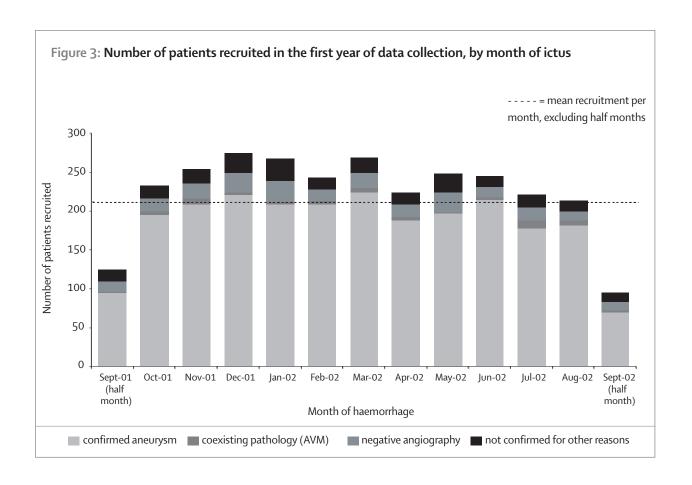
Description of all patients recruited to 3 the study

Clinical data were received for 3174 patients admitted to the 34 NSUs. Of these patients, 2397 had a confirmed aneurysm with no coexisting neurological pathology (75.5%), and 59 had a confirmed aneurysm with coexisting neurological pathology (1.7%) e.g., AVM. No aneurysm was identified in a further 718 (22.6%) patients, because of a negative angiography in 486 (15.1%) patients, and because no angiography was undertaken due to early death in 141 (4.4%) patients or a poor physical condition in 131 (4.1%) patients.

Characteristics of the 3174 patients are shown in Table 3-1. The median age of the 2397 patients with confirmed aneurysms was 52 years. Patients who did not have a confirmed aneurysm had a median age of 59. A higher proportion of patients with a confirmed ruptured aneurysm and no coexisting pathology were female (65.6%) compared to patients with AVM (54.2%) or negative angiography (44.5%). The number of patients recruited to the National Study of SAH are shown in Figure 3 by month of haemorrhage.

The remainder of the report describes only patients who had a confirmed ruptured aneurysm and no coexisting neurological pathology for the following reasons: The other patients form a heterogeneous group with possibly different aetiology, only limited data were collected for these patients; and it was not possible to check completeness of inclusion.

		Patients with confirmed aneurysm		Patients with coexisting neurological pathology (e.g., AVM)		No aneurysm confirmed due to a negative angiography		ysm confirmed other reasons ly death, age)
	n	(%)	n	(%)	n	(%)	n	(%)
Patients	2,397	(75.5%)	59	(1.9%)	486	(15.3%)	232	(7.3%)
Median age in years (range, IQR) [†]	52	(16-90, 43-61)	51	(19-80, 41-58)	51	(16-80, 42-59)	59	(18-86, 48-68)
Age < 65 years	1,981	(82.7)	50	(84.7)	413	(85.0)	150	(64.7)
Missing	2	(0.1)	0		0			
Proportion female	1,570	(65.6)	32	(54.2)	215	(44.5)	154	67.0
Missing	4	(0.2)	0		3	(0.6)	2	(0.9)



4 Characteristics of patients with confirmed ruptured aneurysms

Patient characteristics of the 2,397 patients with confirmed ruptured aneurysms and no coexisting neurological pathology included in the study are shown in Table 4-1. The table shows characteristics separately for patient who were clipped, those who were coiled and those who did not receive a repair. The additional 24 patients who underwent 'other' types of repair (e.g. wrapping with muslin or occlusion with onyx glue) are included in the first column describing all patients, but are not reported separately.

The median age of the patients was 52 years (range 16 to 90 years). 65.6% of the patients were female. The majority of patients (78.9%) were in a good neurological condition on admission. The amount of blood detected on the CT scan was described as medium to heavy in the majority of patients (63.0%). More than two thirds of aneurysm were small (69.7%) and of the majority of aneurysms were in the anterior circulation (88.8%). The most common location for aneurysms was anterior cerebral (36.5%), internal carotid (28.4%), and middle cerebral (23.1%). Table 4-2 gives more details of the location of the aneurysms in 2,169 (90.5%) of the 2,397 patients where the location was known. Concurrent medical conditions were present in 1,059 (44.2%) of patients, the most common condition being hypertension (22.0%), followed by heart disease (5.7%), and chronic obstructive airways disease (COAD) (5.5%).

Table 4-1: Admission characteristics of the 2,397 patients with confirmed ruptured aneurysms and no coexisting neurological pathology, by mode of treatment

		All*	(Coiled	C	lipped	N	o repair
	n	(%)	N	(%)	N	(%)	n	(%)
Number of patients	2,397		905		1,269		199	
Median age in years	52	(43-61,	52	(42-61,	51	(43-59,	60	(49-69,
(IQR, min-max)†		16-90)		18-83)		16-82)		29-90)
65 years old and under	1,981	(82.7)	743	(82.2)	1,093	(86.1)	124	(62.6)
Missing	2		1		0		1	
Proportion female	1,570	(65.6)	611	(67.7)	812	(64.0)	130	(65.7)
Missing	4		2		1		1	
Neurological condition on								
admission ^{††}								
Grade I	1,407	(59.0)	549	(60.9)	789	(62.4)	54	(27.7)
Grade II	474	(19.9)	196	(21.7)	227	(17.9)	45	(23.1)
Grade III	101	(4.2)	36	(4.0)	55	(4.4)	10	(5.1)
Grade IV	240	(10.1)	73	(8.1)	115	(9.1)	50	(25.6)
Grade V	164	(6.9)	48	(5.3)	79	(6.3)	36	(18.5)
Missing	11		3		4		4	
Amount of blood on CT sca	n							
None or light blood	867	(37.0)	340	(38.4)	483	(38.8)	37	(19.6)
Medium	747	(31.9)	283	(32.0)	403	(32.3)	55	(28.0)
Heavy blood	727	(31.1)	262	(29.6)	360	(28.9)	99	(52.4)
Missing	56		20		23		10	
Aneurysm sizeb (<10 mm)	1,613	(69.7)	691	(78.2)	808	(65.9)	100	(55.3)
Missing	84		21		42		18	
Aneurysm site (anterior)	1,927	(88.8)	637	(77.3)	1,138	(97.9)	133	(82.1)
Missing	228		81		107		37	
Concurrent medical condition	ons							
Any reported	1,048	(43.7)	409	(45.2)	514	(40.5)	115	(57.8)
Hypertension	527	(22.0)	203	(22.4)	261	(20.6)	55	(27.6)
IHD	136	(5.7)	50	(5.5)	61	(4.8)	25	(12.6)
COAD	132	(5.5)	53	(5.9)	61	(4.8)	18	(9.1)
Diabetes	54	(2.3)	23	(2.5)	21	(1.7)	8	(4.0)
Epilepsy	26	(1.1)	7	(8.0)	14	(1.1)	5	(2.5)
Other	551	(23.0)	217	(24.0)	265	(20.9)	66	(33.2)
None	1,349	(56.3)	496	(54.8)	755	(59.5)	81	(42.2)

^{*} this column also includes 24 patients who underwent repair procedures other than clipping and coiling (e.g., wrapping and gluing) not reported separately

[†] Median age (25th – 75th percentile, range)

^{††} based on the WFNS grading system

	Left		Mi	Midline		Right		total	
	n	(%)	N	(%)	N	(%)	n	(%)	
Anterior Circulation									
Anterior cerebral	412		-		380		792	(36.5)	
Middle cerebral	227		-		273		500	(23.1)	
Internal carotid	277		-		338		615	(28.4)	
Anterior site missing	7		_		13		20	(0.9)	
Sub total	923		_		1,004		1927		
Posterior Circulation									
Posterior	61		-		56		117	(5.4)	
Basilar	-		125		-		125	(5.8)	
Sub Total	61		125		56		242		
Total	984	(45.4)	125	(5.8)	1,060	(48.9)	2169	100	

5 Management of patients with confirmed ruptured aneurysms

Of the 2,397 patients with a confirmed aneurysm and no coexisting neurological pathology, 2,198 (91.7%) received a repair procedure. Of those repaired, 1,269 (57.7%) were clipped, 905 (41.7%) were coiled and a further 24 (1.1%) underwent other procedures such as wrapping the aneurysm wrapped with muslin or occlusion with onyx glue. A total of 199 (8.3%) patients received no repair.

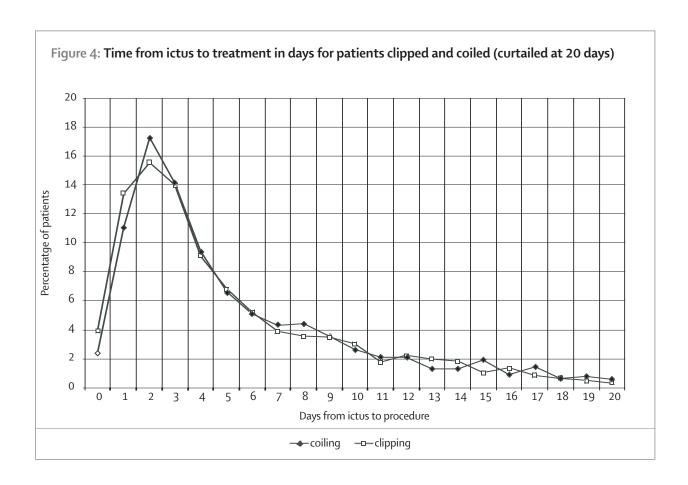
Three quarters of all 2,397 patients were admitted to hospital on the day the haemorrhage occurred.

Approximately one third of all patients reached the NSU the day the haemorrhage occurred, and a third the day after.

Table 5-1 shows that these proportions do not differ

between patients who were clipped and coiled, but a higher proportion of patients who subsequently did not undergo a repair were admitted to the NSU on the same day as their haemorrhage, which may indicate a worse initial condition.

Of the 2,198 patients who underwent a repair procedure over two thirds were treated within 7 days of haemorrhage (32.0% within two days, and 39.3% between 3 and 7 days). Proportions did not differ between patients who were either clipped or coiled as demonstrated by Figure 4. Only 18.0% of patients repaired (clipped or coiled) were treated after 10 days, whereas 54.0% of the 24 patients who received other repair procedures (e.g., onyx gluing) were treated after 10 days.



		All*	C	oiled	Cl	pped	No	repair
	n	(%)	n	(%)	n	(%)	n	(%)
Total patients	2,397		905		1,269		199	
Days from haemorrhage	to							
admission to hospital								
0 days	1,788	(75.3)	657	(73.2)	958	(75.9)	142	(75.7)
1 day	216	(9.1)	92	(10.3)	104	(8.2)	19	(10.1)
2 to 3 days	138	(5.8)	50	(5.6)	81	(6.4)	6	(2.4)
4 to 7 days	149	(6.3)	61	(6.8)	80	(6.3)	7	(4.1)
More than 7 days	83	(3.5)	37	(4.1)	40	(3.2)	5	(4.7)
Missing	23		8		6		8	
Days from haemorrhage								
to admission to NSU								
0 days	842	(35.2)	295	(32.6)	455	(35.9)	75	(40.8)
1 day	714	(29.8)	271	(29.9)	389	(30.7)	44	(23.9)
2 to 3 days	357	(14.9)	138	(15.3)	186	(14.7)	30	(16.3)
4 to 7 days	263	(11.0)	112	(12.4)	134	(10.6)	17	(9.2)
More than 7 days	217	(9.1)	89	(9.8)	104	(8.2)	18	(9.8)
Missing	4		0		1		3	
Days from haemorrhage	to							
procedure (repaired								
patients only)*	2,198		905		1,269			
0 to 2 days	698	(32.0)	278	(31.0)	417	(33.1)	-	-
3 to 7 days	856	(39.3)	358	(39.9)	493	(39.2)	-	-
8 to 10 days	226	(10.4)	96	(10.7)	127	(10.1)	-	-
more than 10 days	401	(18.4)	166	(18.5)	222	(17.6)	-	-
Missing	17		7		10			

The data collection in this study overlapped with the International Subarachnoid Aneurysm Trial (ISAT)¹¹ that compared the efficacy and safety of coiling with clipping. For the first 8 months of the National Study of SAH, from September 2001 to May 2002 when ISAT ceased recruitment, 21 of he 34 NSUs recruited 198 (8.3%) patients into both ISAT and the National Study of SAH. Figure 5 shows the proportion of patients who were coiled by month of recruitment to the National Study of SAH. Our data show that an increase in the proportion of patients who were coiled began when ISAT stopped recruitment (May 2002).

Table 5-2 shows that out of the 2,174 patients who were repaired (clipped or coiled), 37.2% of patients were coiled before ISAT stopped recruitment, compared to 53.8% coiled after ISAT stopped recruitment (p-value =<0.001). The proportion of patients coiled in NSUs that participate in ISAT rose from 44.7% before recruitment stopped to 62.9% after. In NSUs not participating in ISAT but performing endovascular treatment, coiling rose from 27.1% before recruitment stopped to 44.7% after.

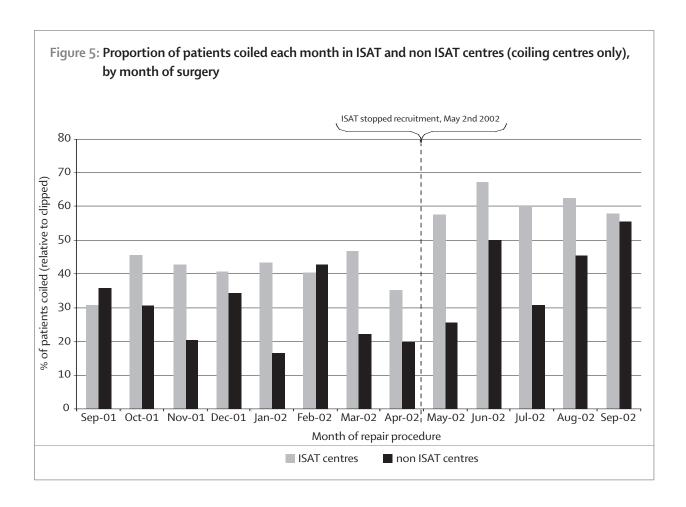


Table 5-2: Proportion	of patient	s coiled a	nd clipp	ed before	and after ISAT ceased recruitment					
	14th Septen	nber 2001 to	o 1st May 2	2002	2nd N	May 2002 – 1	13th Septe	mber 2002	2 Difference in proportion coiled	
	Before IS	SAT halted r	ecruitmen	t	Α	fter ISAT ha	lted recrui	tment	before and after	
		n=1,588				n	=586		ISAT	
	Co	iled	Clip	ped	Co	iled	Clip	pped		
In all NSUs (n=34)	590	(37.2)	998	(62.9)	315	(53.8)	271	(46.3)	16.6%	
NSUs participating in										
ISAT (n=21)	509	(44.7)	631	(55.4)	273	(62.9)	161	(37.1)	18.2%	
Subgroup of patients										
recruited into ISAT	101	(54.3)	85	(45.7)	-		-			
NSUs not participating in	1									
ISAT (n=13)	81	(18.1)	367	(81.9)	42	(27.6)	110	(72.4)	9.5%	
Subset of NSUs not										
participating in ISAT										
with coiling facilities (n=6)) 81	(27.1)	218	(72.9)	42	(44.7)	52	(55.3)	17.6%	

6 Outcomes for patients with confirmed ruptured aneurysms

Patient hospital outcomes

Pre-repair deterioration occurred in 528 (22.0%) of the 2,397 patients with a confirmed aneurysm and no coexisting pathology, as shown in Table 6-1. Pre-repair deterioration caused a delay to the planned procedure in 188 (7.8%) patients, and prevented treatment in 130 patients (5.4%). In the 2174 patients who underwent either clipping or coiling, 389 (17.9%) suffered pre-repair deterioration, causing a delay to the planned procedure in 186 (8.6%) of patients. A high proportion (68.8%) of the 199 patients that did not undergo a repair procedure suffered pre-repair deterioration. The most common probable causes of pre-repair deterioration were cerebral ischaemia (7.5%), hydrocephalus (6.7%) and a re-bleed (5.9%).

Post-repair deterioration occurred in 32.4% of the 2198 patients in whom a repair had taken place. The most commonly recorded probable causes of post-repair deterioration, shown in Table 6-2, were cerebral ischaemia (22.3%), hydrocephalus (6.4%) and a re-bleed (2.0%). It appears that a higher proportion of clipped patients suffered post-repair cerebral ischaemia and a higher proportion of coiled patients suffered a post-repair re-bleed. However, it is important to note that it was not possible to distinguish post-repair deterioration from intra-operative deterioration in these data. Therefore, some intra-operative ruptures in patients during clipping may be recorded as postoperative re-bleeding.

	All*		C	Coiled		Clipped		No repair		
	n	(%)	n	(%)	n	(%)	n	(%)		
All patients	2397		905		1269		199			
Pre-repair deterioration	528	(22.0)	160	(17.7)	229	(18.1)	137	(68.8)		
Delayed procedure	188	(7.8)	84	(9.3)	102	(8.0)	-	-		
Prevent procedure	130	(5.4)	-		-		130	(65.3)		
Probable cause [†]										
Cerebral Ischaemia	179	(7.5)	44	(4.9)	86	(6.8)	49	(24.6)		
Hydrocephalus	161	(6.7)	62	(6.9)	64	(5.0)	34	(17.1)		
Re-bleed	142	(5.9)	30	(3.3)	37	(2.9)	75	(37.7)		
Other	195	(8.1)	56	(6.2)	89	(7.0)	48	(24.1)		
No reason given	2	(0.1)	1	(0.1)	1	(0.1)				

^{*} This column also includes 24 patients who underwent repair procedures other than clipping and coiling (e.g., wrapping and gluing) not reported separately

[†] more than one cause can be recorded

	All repaired*		Coiled		Clipped	
	n	(%)	n	(%)	n	(%)
All patients clipped or coiled	2,198		905		1,269	
Post repair deterioration	711	(32.4)	265	(29.3)	437	(34.4)
Probable cause*						
Cerebral Ischaemia	485	(22.1)	167	(18.5)	312	(24.6)
Hydrocephalus	141	(6.4)	61	(6.7)	79	(6.2)
Re-bleed	44	(2.0)	29	(3.2)	14	(1.1)
Intracranial haematoma	32	(1.5)	3	(0.3)	28	(2.2)
Intracranial infection	17	(8.0)	10	(1.1)	7	(0.6)
General medical	231	(10.5)	90	(9.9)	138	(10.9)
No cause recorded	6	(0.3)	2	(0.2)	4	(0.3)

	All*		Coiled		Clipped		No repair	
	n	(%)	n	(%)	n	(%)	n	(%)
Patients alive at discharge	2,125		840		1,180		82	
Days from admission to NS	SU to disch	arge						
0 to 7 days	117	(5.5)	68	(8.1)	42	(3.6)	7	(8.4)
8 to 14 days	730	(34.4)	329	(39.2)	384	(32.5)	15	(18.3)
15 to 21 days	530	(24.9)	206	(24.5)	300	(25.4)	16	(19.5)
22 to 28 days	299	(14.1)	100	(11.9)	178	(15.1)	16	(19.5)
More than 28 days	449	(21.1)	134	(16.3)	276	(23.4)	28	(34.2)

The length of stay (time in days between admission to NSU and discharge) for the 2,125 patients alive at discharge (88.7%) is shown in Table 6-3. About 40% of the patients were discharged within two weeks. A higher proportion of patients who underwent coiling (47.3%) were discharged within two weeks compared to patients who had undergone clipping (36.1%). Approximately a fifth of patients were discharged after 28 days in the NSU. A higher proportion of patients who were clipped (23.4%) or who had not received a repair procedure (34.2%) were discharged after 28 days compared with coiled patients (16.3%).

Destination at discharge from the NSU is shown in Table 6-4. Nearly half of patients (45.1%) were discharged home, half

to the referring hospital (45.7%), and 9.1% for rehabilitation. In the 199 patients who did not receive a repair procedure, 41.2% died in hospital compared to 7.0% in patients clipped and coiled.

Patient outcome at six months

Of the total 2,397 patients, it was possible to calculate the outcome at six months for 2168 (90.4%) patients. Of these patients, 1,339 (61.8%) had a favourable outcome (good recovery or moderate disability). The percentage of patients with a good recovery did not differ between patients clipped or coiled. Only 19.4% of patients who underwent no repair had a favourable outcome.

		All	C	oiled	Cl	ipped	No	repair
	n	(%)	n	(%)	n	(%)	n	(%)
Number of patients	2,397		905		1269		199	
In hospital mortality	270	(11.3)	65	(7.2)	87	(6.9)	117	(58.8)
Missing	2		0		2		0	
Destination at discharge								
Alive at discharge	2,125		840		1180		82	
Home	984	(46.5)	421	(50.3)	530	(45.1)	23	(28.1)
Referring hosp	960	(45.4)	362	(43.3)	537	(45.7)	50	(61.0)
Rehab unit	170	(8.0)	54	(6.5)	107	(9.1)	7	(8.5)
Missing	11		3		6		2	
Dead at 6 months	317	(14.3)	77	(9.1)	109	(9.3)	129	(70.9)
Missing	179	(7.5)	58	(6.4)	101	(8.0)	17	(8.5)
Glasgow Outcome Score								
(1) Good Recovery	865	(39.9)	357	(43.3)	471	(41.2)	26	(14.4)
(2) Moderate Disability	474	(21.9)	190	(23.0)	274	(24.0)	9	(5.0)
Subtotal:								
Favourable outcome	1,339	(61.8)	547	(66.3)	745	(65.1)	35	(19.4)
(3) Severe Disability	405	(18.7)	148	(17.9)	240	(21.0)	13	(7.2)
(4) Severe Disability [†]	107	(4.9)	53	(6.4)	50	(4.4)	3	(1.7)
(5) Dead	317	(14.6)	77	(9.3)	109	(9.5)	129	(71.7)
Subtotal:								
Unfavourable outcome	829	(38.2)	278	(33.7)	399	(34.9)	145	(80.6)
Missing	229	(9.6)	80	(8.8)	125	(9.9)	19	(9.6)

^{*} This column also includes 24 patients who underwent repair procedures other than clipping and coiling (e.g., wrapping and gluing) not reported separately † The disability was caused by something other than the SAH

7 Risk factors associated with unfavourable outcome (death and disability)

In order to compare outcomes across groups of patients and across NSUs, it is necessary to adjust outcomes for differences in patient characteristics (case mix). In this section, we investigate the association between patient characteristics and outcome.

7.1 Patient characteristics

Patient characteristics included age, sex, neurological condition on admission, blood detected on CT scan, size and site of aneurysm and the presence of concurrent medical conditions. Only patients who were clipped or coiled (n=2,174) were included in this analysis. Patients who were not repaired or who received a different type of repair were excluded as data collection on these patients is more variable. The frequency of missing data was low. Where patients had missing data for risk factors, an additional category was added for each risk factor that indicated that data was missing. Therefore all patients could be used in the analysis regardless of missing risk factor information.

The proportion of repaired patients for whom outcome was available (1969) with an unfavourable outcome according to patient characteristics is shown in Table 7.1. Univariate analysis found that neurological condition on admission was most strongly associated with outcome. Unfavourable outcome ranges from 24.7% in patients with admission WFNS Grade-I (patients with a good neurological condition) to 71.2% in patients with WFNS Grade-V (patients with very poor neurological condition). The risk of an unfavourable outcome increased significantly with age. Female patients appear to have an increased risk of unfavourable outcome.

The amount of blood found on the CT scan is also strongly associated with outcome. Less than a quarter of patients with none or light blood detected on the CT scan had an unfavourable outcome, compared to nearly half the patients with a heavy blood load. The site and size of an aneurysm are also associated with outcome. Patients with aneurysms over

10mm have an increased risk of unfavourable outcome (39.4%) compared to patients with aneurysms less than 10mm (32.0%). Posterior circulation aneurysms are associated with a higher risk of an unfavourable outcome (40.4%) compared to anterior circulation aneurysms (33.2%). Furthermore, the presence of concurrent medical conditions on admission including hypertension, diabetes, COAD, IHD or epilepsy is associated with a higher risk of an unfavourable outcome.

The results of the univariate analysis may not accurately reflect the relationship between outcome and any single factor, since other factors may confound the relationship. To overcome this, multivariate analysis is used. A full model was developed, which included all the risk factors (i.e., all those included in the univariate analysis). Single risk factors were subsequently removed from the full model and the effect of their removal studied with respect to the models overall explanatory power (log likelihood).

7.2 Management factors

Management factors were also tested for their association with outcome. Management factors include clipping or coiling and the timing of repair. A similar proportion of patients clipped (34.6%) and coiled (33.7%) suffered an unfavourable outcome and no difference was detected in the univariate analysis. After adjusting for differences in case mix between the two groups, there was still no difference in outcomes of patients who were clipped and coiled (table 7.3). There was a reduction of risk of an unfavourable outcome in patients treated 2 to 3 days (29.0%) compared to patients repaired on the same day or the day after haemorrhage (41.2%). However, the relationship with timing of repair and outcome was lost when data were adjusted for differences in case mix.

Table 7-1: Outcomes in 1969 repaired patients, for whom outcome was available according to patient characteristics (univariate analysis)

Risk factor	Total patients	Unfavourab	le outcome		Univariate analysis	
		n	(%)	OR	95% confidence interval	P value
Total patients clipped	or coiled 1969	677	(34.4)			
Patient characteristics						
Age (in years)		-	-	1.03	(1.03 to 1.04)	0.000
<45 years	676	166	(28.1)	1		0.000
45 to 54 years	705	231	(35.2)	1.33	(1.03 to 1.72)	
55 to 64 years	601	235	(43.0)	1.81	(1.46 to 2.25)	
65+ years	415	197	(52.7)	2.63	(1.83 to 3.77)	
Missing	0					
Sex						
Male	661	196	(29.7)	1		0.002
Female	1,305	480	(36.8)	1.38	(1.12 to 1.69)	
Missing	3					
Neurological condition	n on					
admission (WFNS grad						
I	1214	300	(24.7)	1		0.000
II	378	142	(37.6)	1.83	(1.44 to 2.34)	
III	88	43	(48.9)	2.91	(1.94 to 4.36)	
IV	164	105	(64.0)	5.42	(3.84 to 7.66)	
V	118	84	(71.2)	7.53	(5.07 to 11.18)	
Missing	7	0				
Blood shown on CT sc	an					
None – light	732	171	(23.4)	1		0.000
Medium	635	221	(34.8)	1.75	(1.37 to 2.24)	
Heavy	563	267	(47.4)	2.96	(2.29 to 3.83)	
Missing	39					
Size of aneurysm						
<10mm	1,376	441	(32.0)	1		0.000
> 10	543	214	(39.4)	1.38	(1.17 to 1.62)	
Missing	50					
Site of aneurysm						
Anterior	1,602	532	(33.2)	1		0.05
Posterior	193	78	(40.4)	1.36	(1.03 to 1.80)	
Missing	174					
Concurrent medical co	nditions					
None recorded	1,131	321	(28.4)	1		0.000
Any recorded	838	356	(42.5)	1.86	(1.54 to 2.26)	
Missing	0		• •		. ,	

Patient Characteristic	OR	(95% CI)	P value
Age (years)	1.03	(1.02 to 1.04)	<0.000
Sex (Female)	1.24	(0.99 to 1.55)	0.1511
WFNS grade on admission			
I	1		<0.000
II	1.59	(1.24 to 2.03)	
III	2.29	(1.53 to 3.44)	
IV	4.48	(3.14 to 6.38)	
V	6.94	(4.39 to 10.98)	
Blood shown on CT scan			
None – light	1		0.003
Medium	1.36	(1.05 to 1.76)	
Heavy	1.57	(1.22 to 2.02)	
Size of aneurysm			
<10mm	1		0.163
> 10	1.24	(1.0 to 1.55)	
Site of aneurysm			
Anterior	1		0.152
Posterior	1.38	(0.98 to 1.93)	
Concurrent medical condition			
None recorded	1		0.0001
Any recorded	1.51	(1.24 to 1.84)	

Table 7-3: Outcomes in 1969 patients, who received a repair procedure (clip or coil) and for whom outcome was available

Risk factor	Total patients			U	Univariate analysis Adju			sted for case mix*		
					95% confidence	95% confiden			:e	
		n	(%)	OR	interval	P value	OR	interval	P value	
Mode of repair						0.586			0.169	
Coiling	821	276	(33.6)	1			1			
Clipping	1,136	393	(34.6)	1.05	(0.81 to 1.38)		1.17	(0.87 to 1.57)		
Days to repair										
(from haemorrha	ge)					0.003			0.177	
0-1 day	342	133	(41.2)	1			1			
2-3	658	174	(29.0)	0.58	(0.45 to 0.75)		0.74	(0.54 to 1.02)		
4-7 days	546	163	(33.0)	0.70	(0.51 to 0.96)		0.92	(0.64 to 1.34)		
7-10 days	223	76	(38.4)	0.89	(0.62 to 1.28)		1.14	(0.76 to 1.69)		
>10 days	388	126	(37.4)	0.85	(0.65 to 1.12)		1.01	(0.73 to 1.40)		
Missing		17								

^{*} Case mix adjustment = age, sex, admission neurological condition, CT blood, site and size of aneurysm and co-morbidity and repair procedure for days to repair; 95% confidence interval (clustered); OR = Odds Ratio; P value = likelihood ratio test

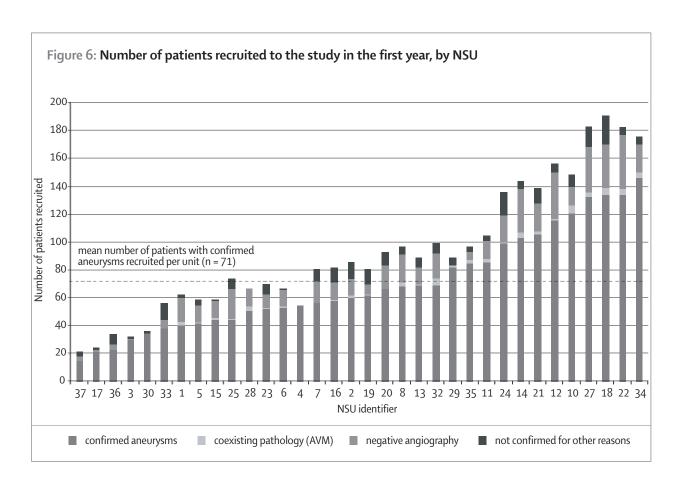
8 Variation by Neurosurgical Unit

One of the primary objectives of this study was to describe the variation in patient characteristics, management and outcome between NSUs. A total of 2379 patients with confirmed ruptured aneurysms and no coexisting neurological pathology were recruited from 34 NSUs. On average, 71 patients were recruited per NSU (ranging from 15 patients to 146). A quarter of NSUs (n=9) recruited less than 50 patients, half (n=17) recruited between 50 and 100 patients, and a quarter (n=8) recruited over 100 patients. The total number of patients recruited by each NSU is shown in Figure 6 and demonstrates that there were NSUs that recruited very few or no patients who did not have a confirmed aneurysm without coexisting pathology.

This suggests that the recruitment of patients without a confirmed ruptured aneurysm, and patients with coexisting neurological pathology was poor in some units.

8.1 Patient characteristics

Key characteristics of patients with confirmed ruptured aneurysms and no coexisting pathology (n=2397) are shown in Table 8-1. There is little variation in the age and sex distribution of patients among participating units, although there are two NSUs with very few patients over the age of 65 years. However, neurological condition on admission does vary considerably. In one NSU, just over half the patients (53.3%) were in good neurological condition on admission



compared to nearly all the patients (94.8%) in another NSU. This may suggest a selective admission policy in some NSUs, but could also be the result of regional differences in patient severity (severity of haemorrhages),

Size and site of aneurysm or the amount of blood showing on the CT scan did not vary greatly between the majority of NSUs. However in one NSU, only 5.3% (2/38) were patients with small aneurysms, compared to 92.2% (107/116) in another. The proportion of patients with some concurrent medical condition on admission (includes diabetes, hypertension, ischaemic heart disease, COPD, epilepsy or other) also varied considerably between NSUs.

The proportion of low risk patients in each NSU was calculated by identifying patients with good neurological condition on admission (WFNS grade I or II), with small (<10mm) anterior circulation aneurysms and who were under the age of 65. This was used as a proxy measure for assessing the variation in patient severity across NSUs. Overall 39.1% of patients were considered low risk, however this varied from 5.3% (2/38) in one NSU to 73.8% (31/42) in another. The range of selected low risk patients across NSU is shown in Figure 7.

8.2 Management of patients

Variation between NSUs in the mode of treatment is shown in Table 8-2. The overall proportion of patients being clipped is 52.9%. As expected, this ranges from 100% in some NSUs (those that do not offer coiling) to as little as 10.5% in other NSUs. The mean proportion of patients with aneurysms that are not repaired is 8.3%. This ranges from 0% to 28.6%. This is because some NSUs only recruited patients that underwent a repair into the study. Figure 8 shows the proportion of patients clipped and coiled by NSU.

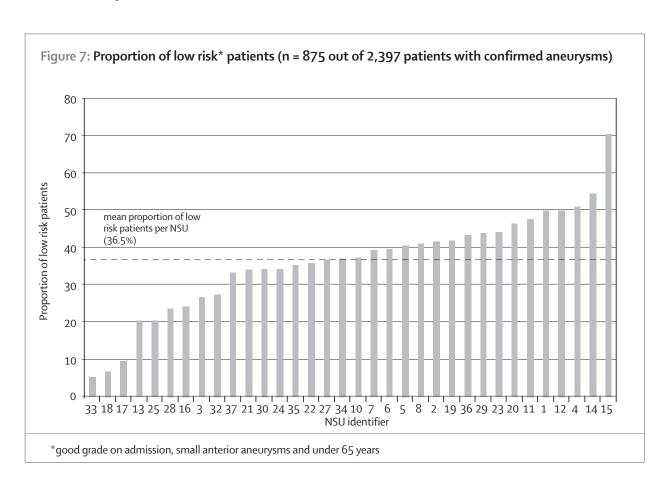


Table 8-1: Variation of patient characteristics by NSU of 2397 patients with confirmed aneurysms and no coexisting pathology repaired or not repaired (n % indicates the overall proportion of patients, percentile and range indicate the variation between NSUs)

	Overa	ll, n (%)	25th to 75th percentile across NSUs	Range (min-max) across NSUs
	n	(%)		
Age under 65 years	1,981	(82.7)	(78.3 - 87.0)	(71.4 - 91.3)
Female	1,570	(65.6)	(62.5 – 69.3)	(55.0 – 78.2)
Good Neurological condition on admission				
(WFNS I or II)	1,881	(78.8)	(74.4 -87.5)	(53.3 - 94.8)
Small aneurysm (<10mm)	1,613	(69.7)	(57.6 – 76.7)	(5.3 – 92.2)
Anterior aneurysm	1,927	(88.8)	(86.2 - 94.1)	(78.7 - 100)
None or light CT blood	867	(37.0)	(26.7 - 47.9)	(16.0 – 68.2)
No concurrent medical conditions	1,349	(56.3)	(50.0 – 64.6)	(31.9 - 77.3)
Selected low risk patients * Age under 65 years with good neurological condition on admission (WFNS grade I – II) and small anterior circulation aneurysm.	875	(39.1)	(32.3 -54.0)	(5.3 – 73.8)

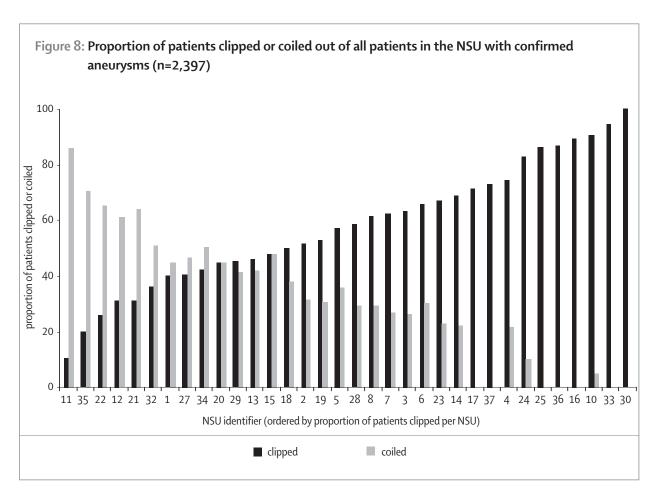


Table 8-2: Variation of patient management, by NSU in 2,397 patients with confirmed aneurysms and no coexisting pathology (n % indicates the overall proportion of patients, percentile and range indicate the variation between NSUs)

	Overall	, n (%)	25th to 75th percentile across NSUs	Range (min-max) across NSUs
	n	(%)		
Coiled	905	37.8	(19.2 – 50.0)	(0 - 86.0)
Clipped	1269	52.9	(50.0 – 80.8)	(10.5 – 100)
Other*	24	1.0	(0 - 1.9)	(0 - 6.7)
No repair	199	8.3	(6.8 – 13.0)	(0 - 28.6)

8.3 Outcomes

Time from haemorrhage to procedure

The median time between the day of haemorrhage and the day of repair is 4 days, with a range of 2 to 10 days between NSUs as shown in Figure 9. Some patients may have had a longer time between haemorrhage and repair because they were referred from another unit. Therefore, NSUs that take a lot of referred patients for coiling from smaller NSUs or non coiling NSUs may have a higher median time to treatment.

Outcome at 6 months

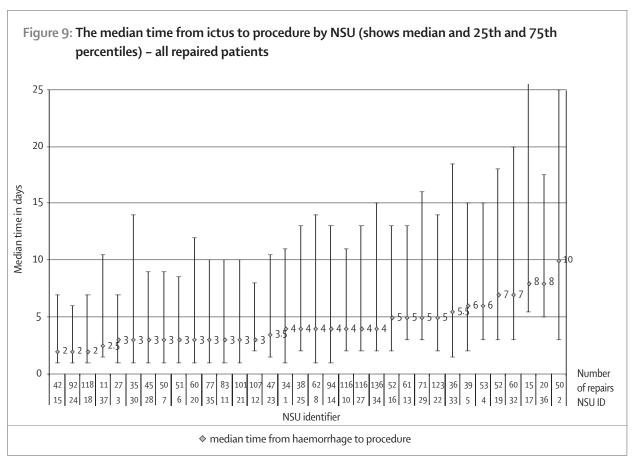
Table 8-3 shows that death occurred in 11.3% of patients in hospital and 14.3% at six months. Mortality did not vary widely between centres. Unfavourable outcome was 38.2% (IQR 29.2% to 44.3% and range 15.0% (3/20) to 70.0%(7/10). Minimum and maximum figures are quite varied. However these results are based on numbers from small units, and the interquartile range is therefore most informative.

There was considerable variation in the amount of missing data across NSUs (not shown in the table). For example, in four NSUs six month outcome information was complete for all patients, whereas in three units outcome information was missing for over 40% of the patients, and in one unit outcome information was missing in over 60% of patients. There was no relationship detected between the proportion of patients with missing outcome data and the overall outcome for a NSU.

An objective of this study was to examine whether there were any differences in outcome among NSUs, and to what degree these might be explained by differences in patient characteristics. This comparison of outcomes is conducted only in patients with confirmed ruptured aneurysms who received a repair procedure (clip or coil) for whom outcomes were available (n=1969)

Table 8-3: Variation of patient outcome by NSU of 2,397 patients with confirmed aneurysms and no coexisting pathology repaired or not repaired (n % indicates the overall proportion of patients, percentile and range indicate the variation between NSUs)

	Overa	ll, n (%)	25th to 75th percentile across NSUs	Range (min-max) across NSUs
	n	(%)		
Death at discharge	270	11.3	(7.6 - 13.1)	(2.3 – 3.3)
Death @ 6 months	317	14.3	(10.4 - 22.0)	(2.4 - 41.7)
Unfavourable outcome	829	38.2	(29.2 - 44.3)	(15.0 – 70.0)



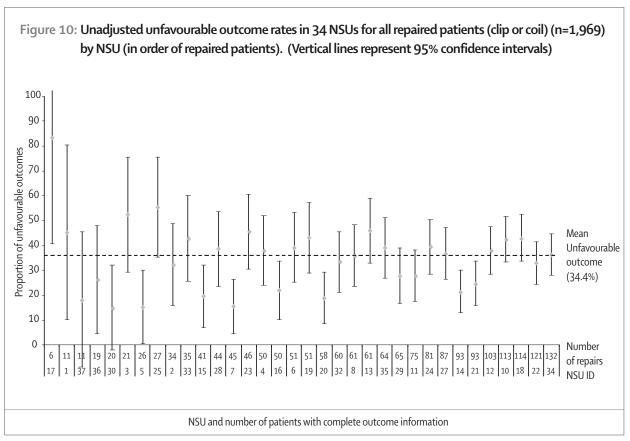
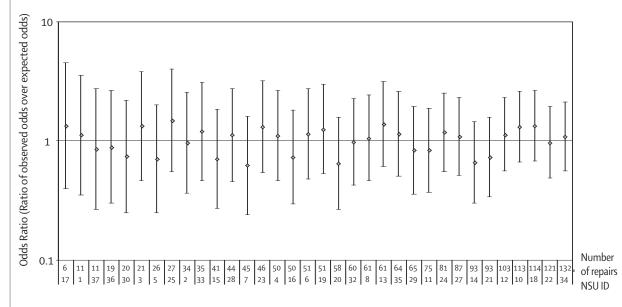


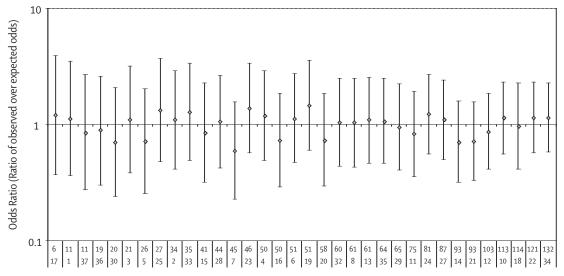
Figure 11: Unadjusted Odds Ratios and 95% confidence intervals in 34 NSUs for all repaired patients (clip or coil) (n=1,969) by NSU (in order of number of repaired patients). Vertical lines represent 95% confidence intervals using multi level modelling. Ratio of observed odds of unfavourable outcome over the expected odds



NSU ranked by number of repaired patients with complete outcome information

Figure 12: Adjusted Odds Ratios and 95% confidence intervals in 34 NSUs for all repaired patients (clip or coil) (n=1969) by NSU (in order of sample size).

Vertical lines represent 95% confidence intervals using multi level modelling. Ratio of observed odds of unfavourable outcome over the expected odds based on age, sex, neurological condition on admission (WFNS grade), amount of blood found on CT scan, size and site of aneurysm, and comorbidities (such as diabetes) present on admission.



Number of repairs NSU ID

NSU ranked by number of repaired patients with complete outcome information

The crude unadjusted proportions of patients with an unfavourable outcome are shown in Figure 10. In this figure, NSUs are ranked by the number of repaired (clipped and coiled) patients submitted to the study. Each rate is shown with a 95% confidence interval. The mean unfavourable outcome rate for all NSUs combined is shown as a dashed horizontal line. This is a crude estimation, without case mix adjustment and without taking into consideration the multilevel nature of the data.

8.4 Multilevel model for comparison of outcomes between NSUs

A multi level model allows us to compare outcomes across NSUs whilst taking into consideration the multilevel (hierarchical) structure of the data and account for differences in case-mix. This approach takes account of the fact that differences in outcomes among patients treated at the same hospital are likely to vary less than outcomes among patients treated at different hospitals.

First, an unadjusted (not controlling for case mix) multilevel model was fitted to show the variation in outcome between NSUs. This is shown in Figure 11. The multilevel analysis shows that although there is variation in unfavourable outcome between NSUs, the confidence intervals include the odds ratio of 1 indicating no statistically significant differences from the mean outcome. In other words, there are no significant outliers. Where sample sizes are small, MLwiN centres the estimate toward the mean. The figure is plotted on an odds ratio scale, where '1' indicates the outcome expected on the basis of the overall results.

A multivariate multilevel model was developed to include case mix variables associated with unfavourable outcome. This model includes age, sex, neurological condition on admission (WFNS grade), amount of blood found on CT scan, site and size of aneurysm and co-morbid conditions present on admission. Adjusting the unfavourable outcome for case mix reduced the variability between NSUs further.

A further multivariate multilevel model demonstrated that management characteristics, such as whether patients were clipped or coiled and the timing of the treatment were not significantly associated with the outcome and did not alter the model. In addition, unit characteristics were also added to the model including whether or not the NSU had coiling facilities, whether or not a NSU participated in ISAT, and how many patients were treated. None of these variables were significantly associated with outcome.

8.5 Conclusions

Without adjusting for case mix and the multilevel nature of the data, there appears to be variation in outcome across NSUs. However, this variation does not remain in the multilevel model. Further reduction of variation is achieved by case mix adjustment.

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APPENDIX 1 Abbreviations and glossary of terms

WFNS

Abbreviations	
Abbreviation	Term
AVM	Arteriovenous malformation
CEU	Clinical Effectiveness Unit of the Royal College of Surgeons of England
CI (95% CI)	Confidence interval
COAD	Chronic obstructive airways disease
CT scan	Computerised tomography
GCS	Glasgow Coma Score
GOS	Glasgow Outcome Score
IHD	Ischaemic heart disease
ISAT	The International Subarachnoid Aneurysm Trial
MRA	Magnetic resonance angiography
NSSAH	National Study of Subarachnoid Haemorrhage
NSU	Neurosurgical unit
OR	Odds ratio
RCS	The Royal College of Surgeons of England
SAH	Subarachnoid haemorrhage
SBNS	Society of British Neurological Surgeons

World Federation of Neurological Surgeons

Glossary of terms

Term	Definition
Aneurysm	See cerebral aneurysm
Aneurysmal subarachnoid haemorrhage	SAH caused by a ruptured aneurysm in the subarachnoid space around the brain.
Angiography	A procedure to examine blood vessels. Used to locate the cause of a subarachnoid haemorrhage.
Arteriovenous malformation (AVM)	A cluster of blood vessels within the brain with abnormal connections. AVMs are prone to bellding.
CEU	Clinical Effectiveness Unit of The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine.
Cerebral aneurysm	An abnormal swelling or bulge in the wall of an artery. Usually, aneurysms develop at the point where a blood vessel branches, because the 'fork' is structurally more vulnerable. It begins as a weak spot in the blood vessel wall, which balloons out of shape over time by the force of the blood pressure. Aneurysms have thin, weak walls and have a tendency to rupture causing haemorrhage into and around brain structures.
Cerebral oedema	Cerebral oedema causes swelling of the brain and mass effect and results from excessive fluid accumulation in response to brain damage.
Cerebral vasospasm	Spasm of blood vessels in the brain causing a decrease of blood supply to parts of the brain A common cause of morbidity and mortality in patients surviving SAH. Cerebral vasospasm can happen between one and 28 days after the initial bleed, with the incidence peaking between days seven and 14.
Clipping (surgical)	A procedure to repair the ruptured aneurysm. A craniotomy is performed and the ruptured aneurysm is located and surgically clipped.
Coiling (endovascular)	A procedure to repair the ruptured aneurysm. The affected blood vessel is located with an angiography. Platinum coils are introduced into the aneurysm via a catheter fed in through the femoral artery, until the fundus is completely filled. The coil mass protects the aneurysm from further bleeding.
Conservative treatment of SAH	Either no treatable cause of the haemorrhage is identified or else the patients clinical status precludes further treatment
Coordinating Centre	CEU
CT scan (computerised tomography)	Identifies the extent of the SAH and can sometimes pinpoint the location of the bleed. A CT scan can identify complications of a subarachnoid haemorrhage, such as communicating hydrocephalus.

Hydrocephalus; Hydrocephalus is the abnormal enlargement of the fluid filled cavities (ventricles) caused Communicating by impairment or obstruction hydrocephalus Lumbar puncture Cerebrospinal fluid is removed using a needle and examined for the presence of blood. A method for determining SAH if no blood is detected on a CT scan CT/ MR angiography Non-invasive methods to visualise brain blood vessels and their associated abnormalities. Occlusion of aneurysm To occlude an aneurysm is to obstruct the flow of blood (e.g., by clipping or coiling) preventing further bleeding from the aneurysm Odds Ratio The odds ratio is an estimate of relative risk, being a good approximation when risks are small. Values below '1' indicate that the risk is reduced, and above '1' the risk is increased. Rebleed Rebleeding of a ruptured aneurysm is a common cause of death in SAH patients. Blood vessels supplying the brain lie in the subarachnoid space underneath the arachnoid layer. Subarachnoid Haemorrhage Bleeding from an aneurysm usually occurs in this space. SAH caused by head injury Traumatic subarachnoid

haemorrhage

APPENDIX 2 Clinical data collection form

			Serial number (office use)	Nº 9964
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Q2 Responsible consultant: initials: Surname:				
sumarne.				
Q3 Patient unit number:				
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Q5 Patient date of birth:	Y Y Y	Q6 Date	e of ictus:	YYY
Date of admission to fir	st hospital:	Q8 Date	e of admission to the property of the property	nis unit:
Q9 a) Was SAH confirmed?				
	yes	no		
Q9 b) If YES, then by what in	vestigation (You	may cross	more than one box	() :
CT scan	Lumb	ar puncture	Autor	osy
Survey : 50				Page:1

Q10 a) Was an aneurysm confirmed?	
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i) By what investigation? (You may cross more than one CT scan MRI sca Angiography Autops ii) Is there coexisting pathology? (e.g. AVM / tumour) yes no IF COEXISTING PATHOLOGY TH	Early death Poor grade Age Poor medical condition Negative angiography HEN
PROCEED NO FURTHER	PROCEED NO FURTHER
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Verbal	1	_2	3	<u>4</u>	5	
Motor	1	_2	Пз	<u>4</u>	5	<u>6</u>
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Q14 b) Aneurysm size:						
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<10 mm	10-2	5mm	>25n	1111		
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018 is the patient participat	ting in the International Study of An	eurysm Treatment (ISAT)?
a rote the patient participal		
	yesno	
	not performed, please specify reas	sons
(You may cross more t	han one box):	
		Untreatable aneurysm
(You may cross more t	han one box):	
(You may cross more t	han one box):	Untreatable aneurysm
(You may cross more to Poor grade Poor medical conditions Q20 a) Did major post-opera	han one box): Age ition Early death ative deterioration occur? (e.g. 1 po	Untreatable aneurysm Other
(You may cross more to Poor grade Poor medical conditions Q20 a) Did major post-opera	han one box):	Untreatable aneurysm Other
(You may cross more to Poor grade Poor medical conditions Q20 a) Did major post-opera	han one box): Age ition Early death ative deterioration occur? (e.g. 1 po	Untreatable aneurysm Other
Poor grade Poor medical condi Q20 a) Did major post-opera on GCS, or requiring	han one box): Age ition Early death ative deterioration occur? (e.g. 1 po transfer back to or delayed dischat yes	Untreatable aneurysm Other Other Dint motor or 2 points verbal arge from HDU/ITU)
Poor grade Poor medical condi 220 a) Did major post-opera on GCS, or requiring	han one box): Age Age Age Age Agition Early death Agitive deterioration occur? (e.g. 1 po Agit transfer back to or delayed dischate Agit yes Probable cause of the deterioration Agit transfer back to or delayed dischate Agit transfer back transfer back to or delayed dischate Agit transfer back transfer	Untreatable aneurysm Other Other Dint motor or 2 points verbal arge from HDU/ITU) n?
Poor grade Poor medical condi Q20 a) Did major post-opera on GCS, or requiring	han one box): Age Age Age Age Agive death Agive deterioration occur? (e.g. 1 po Age Age Age Age Age Age Age Ag	Untreatable aneurysm Other Other Dint motor or 2 points verbal arge from HDU/ITU)
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Poor grade Poor medical condition Occupation Occupation Calcal is a series of the condition of	han one box): Age Age Age Agition Early death Agitive deterioration occur? (e.g. 1 po Agitive transfer back to or delayed dischar Agitive deterioration occur? (e.g. 1 po Agitive deterioration o	Untreatable aneurysm Other Other Dint motor or 2 points verbal arge from HDU/ITU) Rebleeding

Q21 Date of discharge frunit (or death):	om neur	ological	Q22Destination on discharge (Please cross one box): Home Rehabilitation unit
			Dead Referring hospital
Q23 What was the patier	nt's Glas	gow Coma S	Score on discharge?
Eye	1	_2	3 4
Verbal	1	_2	3
Motor	<u></u> 1	2	<u></u>
Hemiparesis		yes	no
Dysphasia		yes	no
Has consultant:			
- completed form y	es 🗌	no	- checked form yes no
Consultant signature:			
			Page: 6
Survey : 50			
Survey : 50			

APPENDIX 3

Follow up questionnaire and patient consent form

	re are also some questions about how things were before then. The quered by you, or by a relative or friend, either alone or together.	uestions can be
This	s questionnaire is in two parts. Please answer all the questions in bot	h parts:
PAF	RT A:	
Q1	Before the haemorrhage were you able to look after yourself at home?	No
Q2	As a result of the haemorrhage do you now need help in the home? (Please mark one box)	
	a) I do not need help or supervision in the home	
	b) I need some help in the home but not every day	
	c) I need some help in the home every day, but I can look after myself for up to 8 hours if necessary	
	d) I could not look after myself for 8 hours during the day	
	e) I need help in the home but not because of the haemorrhage	
Q3	Before the haemorrhage did you need help to shop?	No
Q4	As a result of your haemorrhage do you now need help to shop? (Please mark one box)	
	a) I do not need help to shop	
	b) I need some help, but I can go to the local shops on my own	
	c) I need help to shop even locally, or I cannot shop at all	
	d) I need help to shop but not because of the haemorrhage	
Q5	Before the haemorrhage did you need help to travel?	No

Q6	As a result of the haemorrhage do you now need help to travel? (Please mark one box)	
	a) I do not need help to travel	
	b) I need some help but can travel locally on my own (e.g. by arranging a taxi)	
	c) I need help to travel even locally, or I cannot travel at all	
	d) I need help to travel but not because of the haemorrhage	
Q7	Before the haemorrhage were you working or seeking work (or studying if you were a student)	No
Q8	As a result of your haemorrhage has there been a change in your abilit (or to study if you were a student)? (Please mark one box)	ty to work
	a) I can still do the same work	
	b) I can still work, but at a reduced level (e.g. change from full-time to part-time, or change in level of responsibility)	
	c) I am unable to work or only able to work in a sheltered workshop	
	d) My ability to work has changed, but not because of the haemorrhag	е 🗌
Q9	Before the haemorrhage did you take part in regular social and leisure activities outside the home (at least once a week)? Yes	No
Q10	As a result of your haemorrhage has there been a change in your abili social and leisure activities outside the home? (Please mark one box)	ty to take part in
	a) I take part about as often as before (the activities may be different from above)	
	b) I take part a bit less but at least half as often	
	c) I take part much less, less than half as often	
	d) I do not take part at all	
	 e) My ability to take part has changed for some other reason, not because of the haemorrhage 	

getting on with menus	ge did you have problems in or relatives?	Yes	No
2 As a result of your hae friends or relatives? (I	morrhage are there now problem Please mark one box)	ns in how you	get on with
a) Things are still mucl	h the same		
b) There are occasiona	al problems (less than once a wee	ek)	
c) There are frequent p	problems (once a week or more)		
d) There are constant p	problems (problems every day)		
e) There are problems the haemorrhage	for some other reason, not becau	use of	
your daily life? (Proble	oblems resulting from your haemens sometimes reported: headactight, slowness, memory failure a	hes, dizzines	s, tiredness,
a) I have no current pro	oblems		
b) I have some problem	ns, but these do not interfere with	n my daily life	
c) I have some problem	ns, and these have affected my da	aily life	
d) I have some problem haemorrhage	ns for other reasons, not because	e of my	
Before the haemorrhag	e were similar problems present	? (Please ma	ark one box)
->111	efore, or I had minor problems		
a) i nad no problems be	ns before		
b) I had similar problem			
b) I had similar problem	have you had any epileptic fits?	Yes	No
b) I had similar problem	have you had any epileptic fits?	Yes	

	Office use:
E-llaatualis at	anationts treated for hoomorphogo ground the brain
Follow-up study of	patients treated for haemorrhage around the brain Assessing quality of care
The Society of British Neuros Surgeons hope to assess the eceived by patients with you	surgeons and the Clinical Effectiveness Unit at the Royal College of long-term results of your treatment. This is to improve the treatmen r condition.
he UK and Eire, to complete	king a large number of people, treated in neurological units across a standardised questionnaire describing their current health vill be regarded as strictly confidential.
course, free to not fill in the c	e will be linked to data about your care in hospital. You are, of questionnaire and to receive no further correspondence from us. In k the "no" box below. This will tell us you do not wish to be contacted form even if you do not wish to complete the questionnaire.
follow up study of pat	formation enclosed in the (completed) questionnaire for the ents treated for haemorrhage around the brain Yes \ \ No
follow up study of pati We are also interested in asso send you a further question his form with your questionn urther questionnaire, please	ents treated for haemorrhage around the brain
follow up study of pation We are also interested in associated so send you a further question with your question further questionnaire, please directly, without troubling the	rents treated for haemorrhage around the brain Yes \ \ _No Sessing your health in the longer term, and would like your permission nnaire in the future. Please tick the appropriate box below and return aire in the pre-paid envelope provided. If you agree to being sent a fill in your name and address below so that we can send it to you hospital in which you were treated. Sestionnaire being sent to me in the future and I understand that
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follow up study of pative follow up study of pative for a second you a further question form with your questionn urther questionnaire, please directly, without troubling the lagree to a further quellam under no obligation. Name of Patient Signature	sessing your health in the longer term, and would like your permission nnaire in the future. Please tick the appropriate box below and return aire in the pre-paid envelope provided. If you agree to being sent a fill in your name and address below so that we can send it to you hospital in which you were treated. sestionnaire being sent to me in the future and I understand that on to complete it Yes No Name of Person giving Consent If different from the patient, please state the relationship to patient (i.e. carer, relative)