DYSPHAGIA IN ACUTE STROKE:

ASSESSMENT, NATURAL COURSE AND MANAGEMENT

John Ellul

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DECLARATION

This thesis is the result of my own work. The material contained in the thesis has not been presented, nor is currently being presented, either wholly or in part for any other degree or other qualification.

The research/clinical work was carried out at Royal Liverpool and Broadgreen Hospitals.

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GLOSSARY

A&E	Accident and Emergency
ADL	Activities of Daily Living
BGH	Broadgreen Hospital
BI	Barthel Index
CSA	Clinical Swallowing Assessment
DF	Discriminant Function
DFA	Discriminant Function Analysis
DMP	Dysphagia Management Policy
FNE	Fibreoptic Nasendoscopy
K	Cohen's Kappa
K_2	Quadratically weighted Kappa
LACS	LACunar Syndrome
LOS	Length Of Stay
LRA	Logistic Regression Analysis
MLR	Multiple Linear Regression
MNE	Milk Nasendoscopy
MRC	Medical Research Council
OCSP	Oxfordshire Community Stroke Project
PACS	Partial Anterior Circulation Syndrome
Pexp	Proportion of expected agreement
Pobs	Proportion of observed agreement
POCS	POsterior Circulation Syndrome
RLUH	Royal Liverpool University Hospital

SD	Standard Deviation
Sens	Sensitivity
SLT	Speech and Language Therapist
Spec	Specificity
SSA	Standardised Swallowing Assessment
SSS	Scandinavian Stroke Scale
TACS	Total Anterior Circulation Syndrome
VFS	Videofluoroscopy
+PV	Positive Predictive Value
-PV	Negative Predictive Value
95%CI	95% Confident Intervals

ABSTRACT

Dysphagia in Acute Stroke: Assessment, Natural Course and Management.

J. Ellul, University of Liverpool.

Dysphagia is a frequent and potentially serious complication of acute stroke of all kinds. It may lead to aspiration pneumonia, undernutrition and possibly dehydration, and has been shown to be associated with adverse outcome. Dysphagia is often transient and not recognised during routine clinical practice, especially in the acute stages of stroke before the patient has been assessed by a speech therapist.

To assess the incidence, course and outcome of dysphagia in a representative population of stroke patients, a Standardised Swallowing Assessment (SSA) was developed, validated and used in an observational study involving 757 patients consecutively admitted to two Liverpool teaching hospitals with acute stroke. Interobserver reliability studies were carried out, as well as studies comparing the SSA with instrumental assessments such as videofluoroscopy and fibreoptic nasendoscopy. The management of swallowing problems was audited and a coordinated dysphagia management policy (DMP) was developed and implemented on certain wards, with the remaining wards acting as controls. The effects of the DMP on clinical practice and complication rates were re-audited, and the feasibility of a multicentre study to establish the benefits and costs of coordinated dysphagia management was assessed.

When compared with videofluoroscopy (VFS) the SSA was a more sensitive but less specific indicator of aspiration risk than nasendoscopy. "Unsafe swallowing" on SSA was, however, a better predictor of subsequent chest infection than aspiration on VFS. The SSA was established as a simple, safe procedure which can be reliably used by non specialist staff after a brief period of training.

Over a third of conscious stroke patients had some dysphagia on admission according to the SSA, though a large proportion recovered during the first fortnight. The likelihood of recovery of swallowing could not be consistently predicted from clinical data. Patients with unsafe swallowing had an increased risk of developing chest infection, stayed longer in hospital and had significantly worse functional outcome, although these relationships are confounded by the effects of stroke severity, previous functional status and other prognostic factors. However, after controlling for these factors in a multivariate analysis, dysphagia still appeared to have some independent association with poor outcome.

The audit of routine swallowing management showed that in just under half of the patients with swallowing difficulty, no precautions appeared to be taken to protect against aspiration. A DMP, whereby a simplified version of the SSA was performed by experienced nursing staff on all stroke patients soon after admission, was successfully implemented on three wards. Patients found to have unsafe swallowing were promptly referred for specialist assessment and management. When the audit was repeated, management remained unchanged on the control wards whereas on the intervention wards more precautions against aspiration were taken, mainly but not exclusively in patients with swallowing problems (according to the investigator).

As this study was not designed to measure the effects of the DMP on outcome a causal relationship between dysphagia and adverse outcome, has not yet been established. A large multicentre intervention study is needed to investigate whether better management of dysphagia can improve functional outcome and shorten length of stay in hospital. The feasibility of such a study is supported by the present results.

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Chapter 1

INTRODUCTION

1.a INTRODUCTION

Dysphagia is a frequent event after an acute stroke and may lead to serious consequences. Many patients recover within a few days, if they survive, though swallowing problems persist in a minority. Complications associated with dysphagia, such as aspiration pneumonia or dehydration, whether transient or persistent, may prolong the patient's stay in hospital, hamper efforts at rehabilitation and worsen the functional outcome.

The detection and management of swallowing problems during the first days after a stroke have recently been the subject of much discussion. The answers to key issues relating to management await evidence whilst the present limited knowledge does not allow reliable service planning. Nonetheless guidelines are often introduced without prior evaluation, conflicting with the general principle of evidence based health care, and without any attempt to measure their effects on services.

Traditionally it was taught that only brainstem or bilateral hemisphere lesions caused dysphagia. This belief was based on neuroanatomical observations; supratentorial descending pathways from both hemispheres come into close proximity and relay in the brainstem. Thus either a bilateral hemispheric lesion or a single brainstem lesion can interrupt the neural control of deglutition. Obviously, the neural control of swallowing

is complex and even today is not fully understood.

Just over two decades ago, Meadows [112] reported three cases with swallowing problems and unilateral brain lesions, pointing out that "in rare instances unilateral cerebral lesions may be responsible for dysphagia". Meadows' paper stimulated a more thorough review of the literature, which revealed cases where, as far back as 1898 (Bastian[22] 1898, Pussep and Levin[125]1923, and Tuch and Nielsen[153] 1941), single hemisphere lesions were associated with dysphagia.

Recent studies have shown that dysphagia following an acute stroke is common [16, 66, 93, 130, 159], and seen with all stroke types and territories [2]. There is however a wide variation, from 19% to 79%, in reports of its incidence, reflecting the lack of any standardised approach to the study of dysphagia. Differences in the study population and patient selection, restriction to specific stroke subtypes, variation in detection methods (clinical or radiological), and in the timing of assessment from onset of stroke, may account for this variation.

The assessments employed to detect dysphagia range from clinical swallowing assessments to instrumental assessments. Of the instrumental assessments videofluoroscopy is the most widely used, however other instrumental investigations (eg fibreoptic nasendoscopy) are gaining popularity.

A variety of procedures have been used in clinical swallowing assessments, for both administration of "test materials" and observation of clinical signs. Swallowing

difficulties have been assessed by simple methods involving administering teaspoons or cups of water, or by more complex methods involving "test meals" of different textures including juice, "nectar", frosty fluids, pureed food, ground meat and solids. At the same time a variety of clinical signs, such as coughing, choking, absence of gag reflex and others, have been used to predict aspiration.

A seven item dysphagia screening test [50], carried out on a rehabilitation unit, showed that coughing, during feeding or a 3-oz water swallow test, was a better predictor of swallowing problems than any of the other six items of the test. Studies of this kind indicate the potential of simple clinical swallowing assessments which can be carried out during normal clinical practice. To date, however, none of the available assessments have been adequately investigated or validated for use in the early phases of stroke.

The "modified barium swallow", usually referred to as videofluoroscopy (VFS), is considered to be the "gold standard" for studying the anatomical structure as well as for detecting aspiration. The different stages of this procedure have been described in detail and standardised by J. Logemann [105, 106]. VFS is now quite widely available, though this was not the case in Liverpool at the time this study was performed. Technical reasons can restrict its use and it cannot be carried out by the patient's bedside.

Recently, a new procedure, the fibreoptic nasendoscopy (FNE), has emerged as an alternative technique to videofluoroscopy. The FNE is a widely used

otorhinolaryngological procedure which has been modified and now used for the evaluation of swallowing safety. Although published experience of its use in detecting swallowing abnormalities is very limited, it has been assumed to be accurate and safe.

Dysphagia may lead to aspiration pneumonia [5, 66] and potentially to dehydration and malnutrition. Chest infection, which may be caused by aspiration of saliva, gastric contents or swallowed food, is an important cause of mortality after the first week [156], and is associated with adverse functional outcome. Even if the ultimate outcome is not significantly worsened, prolongation of hospital stay may have serious resource consequences and affect patient morale.

Poor outcome cannot, however, be attributed only to complications following swallowing problems. Dysphagia itself may be an independent predictor of decreased functional outcome, although it is confounded by stroke severity and other prognostic factors. To date, there have been no specific studies of the natural history of dysphagia and our knowledge relies on data collected on a relatively small number of patients in the course of studies in which dysphagia was not the primary area of investigation.

The development of dysphagia management policies requires an understanding of the natural history and course of dysphagia. Knowledge of the current methods used for the detection and management of dysphagia is also necessary if practice is to be improved.

1.b AIMS OF THE STUDY

The aims of this study can be summarised as follows:

A. To develop and validate a Standardised Clinical Swallowing Assessment

B. To study the Natural History of Dysphagia

C. To study the Effects of Dysphagia on Outcome

D. To audit the Current Management of Dysphagia during the Acute Stages of Stroke

E. To identify Deficiencies in Current Practice and Target Areas for Intervention

F. To test the Feasibility for a Coordinated, Multicentre Dysphagia Management Policy

The first step was to develop and validate a standardised bedside swallowing assessment (SSA). To study dysphagia in a large number of patients early after an acute stroke requires a simple, flexible and safe swallowing assessment. This assessment should reliably identify patients at risk of aspiration or with preventable complications. It should be simple enough to be carried out at the patient's bedside by non-specialists.

The SSA was developed according to these principles, and then compared with instrumental swallowing assessments to establish its accuracy alongside the traditional "gold standard" (videofluoroscopy) as well as the newly developed alternative procedure (fibreoptic nasendoscopy).

Patients were studied using the SSA soon after their stroke and followed up to establish the incidence and course of dysphagia. The effects of dysphagia on the incidence of chest infection and outcome were also examined.

A survey was carried out in two large teaching hospitals to establish whether any systematic attempts were being made to detect swallowing problems during the acute stages of stroke and whether the management of dysphagia was appropriate. Areas of need were identified and an intervention programme devised. Finally, the feasibility of implementing such a dysphagia management policy was examined, and preliminary data collected to assess its impact on patient care.

1.c OUTLINE OF THE THESIS

In Chapter 2 all aspects of current knowledge of dysphagia in acute stroke are reviewed. This includes the definitions of dysphagia and aspiration, the methods developed so far to detect swallowing problems, and the value of their findings to predict complications and adverse outcome. The course of dysphagia, the incidence of complications, and outcome have also been examined. Finally, the current methods used for the detection and management of dysphagia are described.

In Chapter 3 the timing and the type of clinical assessments carried out for this study are described. More detailed information about the methods used in specific study areas, however, are given at the beginning of each chapter.

In Chapter 4 the development of a clinical Standardised Swallowing assessment (SSA) is described. The characteristics of the SSA and the relationship of each SSA item with the overall judgement of swallowing safety are examined. The general principles of validity and reliability are outlined and then applied to the SSA. The content validity and interobserver reliability of the SSA are discussed.

In Chapter 5 the results of SSA and fibreoptic nasoendoscopy are compared with those of videofluoroscopy. The accuracy of these investigations to detect patients at risk of aspiration is examined, as well as their ability to predict chest infections.

In Chapter 6 the incidence and course of dysphagia during the first four weeks after stroke are considered. The general characteristics of the study population are described first, then the incidence of dysphagia in different prognostic subgroups is shown. Factors which might predict swallowing improvement are then investigated, using a discriminant function analysis.

In Chapter 7 the relationship of dysphagia to in-hospital infections, length of stay in hospital, and outcome at discharge, are examined. The independent effects of dysphagia on outcome, after controlling for potential confounding factors, are studied using multiple linear regression analysis.

In Chapter 8 an audit on current methods used by ward staff for the detection and management of dysphagia early after a stroke is described. The development of a dysphagia management policy and its implementation on three "intervention" wards are

also described and the results discussed.

In Chapter 9 the findings of this study are summarised and future research needs discussed.

In Appendix A more recent interobserver studies using the SSA are described.

Chapter 2

SYSTEMATIC REVIEW OF THE LITERATURE

2.a OUTLINE OF PHYSIOLOGY OF SWALLOWING

The act of swallowing is highly complex, involving over 50 pairs of muscles and coordinated by the central nervous system. For convenience, it is divided into three phases.

1) Oral phase of deglutition

The ingestion and mechanical formation of the bolus, as well as the initiation of swallowing reflex occur during this phase, which is almost entirely voluntary. The total transit time of the bolus in normal individuals is approximately 1 second for all food consistencies, age and sex [106].

The "pattern generator" which is an ill defined area of the medullary reticular formation in the lower brainstem [90] orchestrates the activities of the fifth, seventh and twelfth cranial nerves, eliciting mastication. This activity is controlled by higher forebrain centres. Thus, lesions in the cortical hemispheres and descending corticobulbar pathways may cause difficulties in initiating the swallow and chewing.

2) Pharyngeal phase of deglutition

This phase begins when the swallowing reflex is triggered at the anterior faucial arch and continues until the bolus passes through the cricopharyngeus muscle. Normal

pharyngeal transit time is less than one second, regardless of age or food consistency [90].

The neurular control appears to be located within the boundaries of the nucleus of the solitary tract [51] and receives descending inputs from the forebrain. However, animal studies suggest that non-capsular pathways from the hypothalamus, the limbic system (especially the amygdala), and the basal ganglia contribute to this phase of swallowing [24, 79].

3) Oesophageal phase of deglutition

The combined effect of a negative intrathoracic pressure and the physical distention of the oesophagus caused by the bolus act to elicit reflex peristalsis. The normal oesophageal transit varies between 8 to 20 seconds [106].

The nucleus of solitary tract through the vagus nerve stimulates directly the striated muscles of the upper third of the oesophagus and indirectly the smooth muscles via the enteric nervous system [150]. The oesophageal smooth muscle is able to generate peristalsis even in the absence of innervation of the central nervous system [150].

2.b DEFINITIONS

Dysphagia can be described as a subjective complaint of swallowing difficulty, or objectively observed clinical signs indicating dysfunction during or immediately after swallowing. Final consensus on the definition of dysphagia is still, however, lacking.

By contrast, the diagnosis of aspiration is based on signs detected by instrumental assessments and can be defined as penetration of saliva, fluids or food below the level of the true vocal cords before, during or after swallowing. When no cough or other outward signs of difficulty are observed, it is described as "silent aspiration" and "audible aspiration" when respiratory distress, coughing, choking, or a change in voice quality (wet, hoarse, or gurgly voice) occurs [84, 146, 155].

Although the definition of aspiration now appears to be widely accepted, early studies [7, 126, 131] regarded the entry of contrast material into the laryngeal vestibule, and even in some cases down to the rima glottis and trachea, to be within normal limits. In 1982 Ekberg studied normal subjects [57] as well as dysphagic patients [56], during a modified barium swallow. He described penetration of contrast material into the laryngeal vestibule as a sign of "dysfunction" because it occurred only in 5% of normal volunteers compared to 41% of dysphagic patients. On the other hand, penetration of contrast medium into the vestibule below the subepiglottic level never occurred in normal individuals compared to 16% of patients with dysphagia, and should be therefore regarded as a serious abnormality.

Aspiration may occur during any stage of swallowing. In a study by Veis et al [155] out of 12 aspirators, 7 aspirated before, 1 during, 2 after swallowing, and 2 in more than one stage. Aspiration occurring before the initiation of the pharyngeal stage is most frequently due to a delay in the pharyngeal response, during which the material falls into the open airway [130]. Inspiration of the pooled residual material may account for the cases in which aspiration occurs after swallowing [130].

2.c DETECTION OF DYSPHAGIA

2.c.1 Radiological evaluation

Videofluoroscopy (VFS) has been widely employed in the detection of swallowing problems. The procedure has been thoroughly described by Logemann [105, 106]. Anterior and lateral fluoroscopic views of the oro-pharynx are recorded using a video time counter, whilst radiopaque material is swallowed. Liquid barium, barium pastry, and biscuits coated with barium may be given in controlled amounts unless the patient aspirates any consistency. The recording can be reviewed in slow motion, frame by frame, and abnormalities identified. VFS is safe, requires only 90 to 120 seconds of fluoroscopy time [85, 106] and even in the event of aspiration, it is claimed that a small amount of barium in the airways is not harmful [63].

This technique provides detailed information on the nature of the disturbance, the presence and aetiology of aspiration [59]. Table 2.c.1 illustrates the most frequently observed swallowing disorders. In Veis et al [155], 76% of the patients exhibited more

Table 2.c.1 Frequency of swallowing abnormalities during videofluoroscopy.
(Figures show percentage (%) of all patients studied with given abnormality)

	Oral preparatory dysfunction	Abnormal/reduced lingual movements	Epiglottic dysfunction	Cricopharyngeal dysfunction	Delayed swallowing reflex	Reduced pharyngeal peristalsis
Ekberg [56]						
All patients (n=250)			33%	22%		10%
Aspirators (n=103)			63%	22%		22%
Horner [82]						
All patients (n=70)	57%				91%	66%
Aspirators (n=34)	53%				91%	82%
Horner [83]						
All patients (n=47)	68%				92%	57%
Aspirators (n=24)	56%				100%	75%
Horner [84]						
All patients (n=21)	71%				90%	76%
Aspirators (n=7)	64%				91%	73%
Kidd [93]						
All patients (n=60)		64%				
Aspirators (n=25)		71%				
Veis [155]						
All patients (n=38)		50%			82%	58%

than one swallowing disorder, although right hemisphere strokes tended to show abnormalities in only one abnormality. By far the most frequent combination was a delayed swallowing reflex with reduced pharyngeal peristalsis.

Swallowing dysfunction does not always lead to aspiration, however. In Horners' studies [82, 84], for instance, abnormalities of oral preparation, reflex initiation, and pharyngeal motility did not distinguish the aspirators from non-aspirators.

2.c.2 Clinical Swallowing Assessment

A variety of clinical assessments have been described in the literature, though the techniques and the clinical signs observed differ from study to study and thus, direct comparisons cannot always be made. Moreover, few of them were designed to be used in the early stages of a stroke or as a basis for taking clinical decisions, and most require more rigorous validation.

Most clinical swallowing assessments (CSAs) have a preliminary phase during which factors that might be correlated to swallowing safety are tested. These include assessments of conscious level, oromuscular function, gag reflex, pharyngeal sensation, quality of voice, voluntary cough, etc. Fluids and/or solids are then administered. Table 2.c.2 shows that patients were usually asked to sip different amounts of water from a cup or a glass, and in some instances (when speech and language therapists were involved) to try different consistences and texture of food. They were then observed for signs of pooling in the laryngeal inlet (change of voice quality), or aspiration (eg

Table 2.c.2 Swallowing assessment techniques used and clinical signs observed in stroke studies.

Literature	Swallowing Assessment Technique	Clinical Signs observed
Barer [16]	10mls of water from a cup or a beaker	Delayed swallowing, coughing
DePippo [49]	3-oz of water from a cup	Coughing, wet-hoarse voice
DePippo [50]	The Burke Dysphagia Screening Test	Coughing
Gordon [66]	50mls of water from a beaker or medicine container glass	Inability to complete, choking more than once on two occasions
Gresham [69]	Test meal: thin fluid, fine puree, coarse puree	Absent swallowing and gag reflex, coughing, choking, voice quality
Horner [84]	Not specified	Subjective complains (eg cough, choking, discomfort), gag and swallowing reflex
Kidd [93]	50mls of water in 5ml aliquots	Choking, coughing, change of voice quality
Nathadwarawala [115]	Up to 150ml water from a glass	Swallowing speed (ml/s), coughing, residual volume,
Splaingard [146]	Test meal: liquids (juice, nectar, frosty), pureed foods, ground meat, solids	Vocal quality, throat clearing, cough, respiratory distress, swallow reflex, manipulation and control of bolus
Teasell [149]	Retrospective - from patient's notes	* Choking, dysarthria, wet-hoarse voice
Wade [159]	Patients were asked to swallow water from cup	Choking, obvious difficulty or abnormality, slow swallowing (patient's opinion was sought as to normal swallowing speed)

* These criteria were used to select patients with dysphagia before undergoing videofluoroscopy

coughing, respiratory distress, etc). Finally, investigators made a judgement on whether or not dysphagia was present.

Obviously, a clinical swallowing assessment is relatively easy to perform, but how does it compare with VFS (the conventional "gold standard"). Four studies [49, 93, 144, 146] provided data allowing this comparison and the results are shown in Table 2.c.3. There was a wide variation in both sensitivity and specificity.

Another method of evaluating CSAs is to examine their value in predicting complications, thus, avoiding comparisons with other instrumental methods. The literature provided limited assistance as information was available from only three sources.

Patients who failed the Burke dysphagia screening test [50] had a 7.7-fold higher risk of developing pneumonia, "recurrent upper airway obstruction" or death, compared to those who passed the test. This test requires a present/absent response to seven items and the presence of any one of these features means that the test is failed (Table 2.c.4). However, coughing during feeding or 3-oz water test alone, performed better (relative risk 13.7) in predicting complications than all the other six items including the test's total score. This finding implies that a simple assessment can still be reliable and sensitive. (There is an error in the reference [50] Table 2: the likelihood ratio was erroneously given instead of relative risk). Finally, in Gordon's [66] and Smithard's [143] studies patients found with swallowing problems by a CSA had approximately between 2 to 2.5-fold increased risk of developing a chest infection compared to those without swallowing difficulties.

Table 2.c.3 Accuracy of the clinical swallowing assessment (CSA: dysphagia present or absent) compared with videofluoroscopy (VFS: aspiration present or absent).

Literature	Delay between CSA and VFS	Sensitivity	Specificity	+ Predictive value	- Predictive value
DePippo [49]	Not specified	80%	54%	59%	76%
Kidd [93]	Not specified but <72 hours	80%	86%	80%	86%
Smithard [144]	<24 hours	70%	66%	36%	89%
Splaingard [146]	<72 hours	42%	90%	75%	70%

Table 2.c.4 The seven items of the Burke Dysphagia Screening Test [50] and their value in predicting complications*.
[Sensitivity (Sens), Specificity (Spec), Positive predictive value (+PV), Negative predictive value (-PV) and relative risk with 95% confident intervals (95%CI)]

	Sens	Spec	+ PV	- PV	Relative risk (95%CI)
1. Bilateral hemispheric stroke	17%	94%	22%	92%	2.9 (1.8-11.3)
2. Brainstem stroke	17%	93%	18%	92%	2.3 (0.6-9.3)
3. History of pneumonia in acute phases of stroke	25%	88%	17%	93%	2.2 (0.7-7.5)
4. Coughing during feeding or 3-oz water test	92%	60%	18%	99%	13.7 (1.8-103)
5. persistent failure to consume one half of meals	17%	90%	13%	91%	1.7 (0.4-6.8)
6. Prolonged time required for feeding	17%	91%	14%	92%	1.8 (0.4-7.3)
7. Non oral feeding program in progress	17%	93%	18%	92%	2.3 (0.6-9.3)
Failing the test (failing any of the above)	92%	44%	13%	98%	7.7 (1-57.6)

* A total of 12 out of 139 patients developed complications (ie pneumonia, recurrent "upper airway obstruction", or death)

Other clinical tests [62] or scores [43, 48], which have been developed to detect dysphagia, are more appropriate for patients with chronic diseases affecting swallowing or for epidemiological studies [102] than for stroke patients.

2.c.3 Fibreoptic nasendoscopy

The use of flexible fibreoptic nasendoscopy (FNE) for the evaluation of swallowing safety was described by Langmore in 1988 [100] and subsequently by Bastian [19, 20, 21]. The standard otorhinolaryngologic procedure was modified to focus on the pharyngeal stage of swallowing.

The distal end of the nasendoscope is located in the oropharynx at the level of the soft palate. This allows a view of the base of the tongue, the epiglottis, valleculae, pyriform fossae and laryngeal inlet. Direct observation of the act of swallowing is made whilst the patient swallows controlled amounts of milk [100] or natural dye [19]. This procedure has been described as accurate, inexpensive, safe, cost effective and well tolerated [52, 97, 98, 161, 162]. FNE has also been regarded as a safe and valuable procedure in the elderly [64, 70], which does not interfere with the function of the structures observed [121], and its use has been extended to the assessment of dysphonia [117].

The oral phase is assessed indirectly for signs of poor tongue function by observing whether milk or dye dribble over the back of the tongue. Although the pharyngeal phase is observed directly, the laryngeal view is momentarily obscured, so that the diagnosis of aspiration must be inferred from the presence of residual material in the

upper airway after the swallow. Pooling of material in the vallecula and pyriform fossa can be witnessed directly. Normal swallowing occurs rapidly so that videorecording has been advocated for closer assessment.

There is, however, limited experience with the use of FNE in detecting dysphagia in acute stroke patients. Wilson et al [163] reported the use of FNE in 15 normal subjects and 15 patients complaining of dysphagia, of whom one third had suffered a stroke. None of the normal subjects aspirated compared to 73% of the dysphagic patients. FNE was compared with VFS in 21 subjects, affected by a wide variety of pathologies [99]. The sensitivity of FNE for detecting aspiration was 88%, the specificity 92%, the positive predictive value 88% and the negative predictive value was 92%.

2.c.4 Other techniques

Many other techniques have been experimentally used for the investigation of dysphagia. These include manometry [138], manofluorography [109, 110], ultrasound scanning [147, 148], electromyography [122, 145], scintigraphy after swallowing radiolabelled material [60, 74, 113, 141], as well as techniques measuring the pharyngeal acceleration response [129] and speed of swallowing [115]. These techniques have had little clinical use in acute stroke, and are therefore outside the scope of this overview.

The electrophysiology of normal and abnormal swallowing is also being investigated using transcortical magnetic stimulation.

Magnetic Resonance Imaging or X-ray Computed Tomography brainscanning cannot be used for the detection of dysphagia [5] as the observed structural abnormalities may bear little relation to dysfunction [47], and very small or very acute lesions [3, 133] may not be detected. Severe strokes involving large vascular territories tend, however, to be associated with a high risk of aspiration [2].

2.d INCIDENCE OF SWALLOWING PROBLEMS IN ACUTE STROKE

2.d.1 Incidence of dysphagia

Table 2.d.1 summarises the results of published studies using clinical swallowing assessment (CSA) to detect dysphagia early after stroke. Of the patients who were assessed within 2-3 days of onset up to 50% were found to have swallowing problems.

The lower incidence of dysphagia (29%) in Barer's study [16] may be explained by the exclusion of patients with severe dysphagia, who were unable to take oral medication. The data from the three studies [16, 93, 143], which assessed consecutive patients in the early phase were combined and the overall proportion of patients with dysphagia estimated. Of the combined study population (n= 538), 35% had some degree of swallowing difficulties.

In two further studies [66, 159] consecutive stroke patients were assessed by a CSA within the first week (<1% seen after 7 days). On average, 43% were found to have dysphagia. Overall, in all 5 studies with "early" swallowing assessments, 39% of the 1081 acute stroke patients had swallowing problems.

Table 2.d.1 Proportion of patients with clinically defined dysphagia in studies with early swallowing assessments.

(Patient selection: consecutive acute stroke patients)

Literature	Delay between stroke onset and assessment	n	% dysphagia	Unconscious patients excluded	Comments
Barer [16]	≤48 hours	357	29%	Yes	Severe swallowing problems excluded Unilateral hemispheric lesions only
Kidd [93]	<72 hours	60	42%	Yes	
Smithard [143]	≤24 hours	121	50%	Yes	
Combined [16] [93] [143]		**538**	**35%**		
Gordon [66]	61% <2 days 27% 2-4 days 9% 5-13 days	91	45%	No	
Wade [159]	<1 week	452	43%	Yes	Included strokes in community
Combined [66][159]		**543**	**43%**		
COMBINED ALL		**1081**	**39%**		

Other studies (Table 2.d.2), which had swallowing assessments performed over a month after stroke (if specified) at selected populations, were too heterogeneous to be directly compared. Nonetheless, between 22% to 61% of these patients were found to have dysphagia.

2.d.2 Incidence of aspiration and silent aspiration

In two of the above studies videofluoroscopy (VFS) was also carried out. Table 2.d.3 shows that in Smithard's study [143], aspiration was detected in 21% of the patients compared to 42% in Kidd's study [93]. Of the combined 154 cases, 29% aspirated at VFS.

Many studies have used VFS to investigate stroke patients with clinically detected dysphagia. Table 2.d.4 shows that 44% to 78% (average 55%) of these patients aspirated contrast material, and that a high proportion of the aspirations occurred silently. However, judging from the timing of the VFS and the proportion of brainstem and bilateral strokes, these patients mostly had severe persistent swallowing problems.

Table 2.d.5 summarises the results of a heterogeneous group of other studies using VFS. The proportion of cases who aspirated varied (19% to 70%), but the different patient selection criteria, stroke territory, and the timing of the investigation do not allow for comparisons.

Table 2.d.2 Proportion of patients with clinically defined dysphagia in studies with late swallowing assessments.

Literature	Patient selection	Delay between stroke onset and assessment	n	% Brainstem / %Bilateral stroke	% dysphagia	Comments
DePippo [49]	Selected by criteria indicating dysphagia*	5±3 weeks	44	23% / 7%	61%	
DePippo [50]	Consecutive admissions to rehabilitation unit	5±3 weeks	139	12% / 6%	59%	
Gresham [69]	Consecutive referrals to Speech Therapy	Not specified	98	------	54%	Study population was 61% of the total hospital admissions
Splaingard [146]	Consecutive admissions to rehabilitation unit	Not specified	107	------	22%	19% had no-stroke disease

* Clinical screening tools described by Horner [81] and Logemann [105] as in DePippo [49]:
1) Bilateral hemispheric strokes; 2) Brain-stem strokes; 3) Pneumonia during the acute phase of stroke; 4) Coughing associated with feeding 5) Failure to consume half of the meal; 6) Prolonged feeding time 7) Non oral feeding

Table 2.d.3 Proportion of patients with aspiration in studies with early videofluoroscopy (VFS).

(Patient selection: consecutive acute stroke patients. Unconscious patients and those unable to undergo VFS were excluded)

Literature	Delay between stroke onset and assessment	n	% aspiration
Kidd [93]	<72 hours	60	42%
Smithard [143]	<72 hours	94	21%
Combined [93] [143]		**154**	**29%**

Table 2.d.4 Proportion of patients with clinically detected dysphagia showing aspiration during videofluoroscopy.

Literature	Delay between stroke onset and assessment	n	% Brainstem / %Bilateral stroke	% aspiration	% silent aspiration
Hollas [80]	Median 4 weeks	114	14% / 10%	54%	39%
Horner [84]	Mean 2.8 months	21	24% / 43%	48%	38%
Combined [80] [84]		**135**		**53%**	**39%**
DePippo [49]	Mean of 5±3 weeks	44	23% / 7%	45%	
Schmidt [137]	Mean 62 days	59	------	44%	
Teasell [149]	Mean 39 days	54	33% / 15%	78%	
Combined ALL		**292**		**55%**	

Table 2.d.5 Proportion of aspiration during videofluoroscopy in other studies.

Literature	Patient selection	Delay between stroke onset and assessment	n	% Brainstem/ %Bilateral stroke	% aspiration	% silent aspiration
Chen [34]	Referred by speech therapists	<I month	46	7%/---	33%	
Horner [81]	Consecutive referrals to Speech Therapy	Mean 46 days (1-575 days)	23	100% / ---	70%	
Horner [82]	Consecutive referrals for evaluation of swallowing	Not specified)	70	--- / 100%	49%	
Horner [83]	Referred for evaluation of swallowing	Mean 2.9 moths (1-24 months)	47	13% / 64%	51%	28%
Johnson [89]	Referred for evaluation of swallowing	Not specified	60	------	46%	
Robbins [130]	Not specified	21±2days	16	0% / 0%	19%	
Splaingard [146]	Consecutive referrals for evaluation of swallowing	Not specified	107*	------	40%	20%
Veis [155]	Consecutive referrals to VFS	<4 months	38	11% / ---	32%	

* 19% suffered brain injury or chronic neuromuscular disorders

2.e MARKERS OF DYSPHAGIA OR ASPIRATION

Markers of stroke severity, such as older age [16, 66, 93], decreased conscious level [16, 66, 93], reduced sitting balance [66], gaze paresis [16], visual field deficits [93], perceptual disorders [93], dysphasia [93], facial weakness [66, 93], dysarthria [66, 81, 84] and abnormal tongue movement [66, 93], are all associated with dysphagia. When adjustments were made to allow for overall stroke severity, Barer [16] found that only gaze paresis was still significantly correlated to dysphagia, whereas Kidd [93] found that pharyngeal sensation, together with the clinical swallowing assessment, were independent predictors of aspiration in videofluoroscopy.

Many of the above studies have examined only a small number of subjects. Data were, therefore, combined (when possible), so that the overall sensitivity, specificity and relative risks associated with each of the neurological signs could be estimated.

Dysarthria (Table 2.e.1) was very sensitive (97%) though not specific in identifying swallowing problems. In the presence of dysarthria the relative risk of having swallowing problems was 7.6, though the 95% confidence intervals were still wide (1.9-28.9) because of the high prevalence of dysarthria (79% of the combined 124 patients were dysarthric).

Dysphonia (Table 2.e.2) and facial weakness (Table 2.e.3) were also very sensitive but less specific in detecting swallowing abnormalities, with moderate relative risks (1.8 and 3.1 respectively) of having swallowing problems.

Table 2.e.1 **Dysarthria** as a predictor of clinical detected dysphagia or aspiration during videofluoroscopy.
[Sensitivity (Sens), Specificity (Spec), Positive predictive value (+PV), Negative predictive value (-PV)]

Literature	n	Sens	Spec	+ PV	- PV	Relative risk (95%CI)	p
Gordon [66]	81*	96%	49%	65%	92%	14.3 (2.1-98.8)	
Horner [84]	21	All	patients	dysarthric			
Combined [66] [84]	**102**	**98%**	**41%**	**56%**	**96%**	**14 (2-96.3)**	**<0.01**
Horner [81] **	22*	94%	---	70%	---	0.7 (0.5-0.9)	
Combined ALL	**124**	**97%**	**37%**	**58%**	**92%**	**7.6 (1.9-28.9)**	**<0.01**

* Information was not available in all study cases
** Included only brainstem strokes

Table 2.e.2 **Dysphonia** as a predictor of clinical detected dysphagia or aspiration during videofluoroscopy.
[Sensitivity (Sens), Specificity (Spec), Positive predictive value (+PV), Negative predictive value (-PV)]

Literature	n	Sens	Spec	+ PV	- PV	Relative risk (95%CI)	p
Horner [83]	45	68%	9%	42%	22%	2.6 (0.8-9)	
Horner [84]	18	91%	40%	62%	80%	3.1 (0.5-18.8)	
Linden [103]	15	90%	100%	100%	67%	3 (0.61-14.68)	
Combined [83] [84] [103]	**81**	**89%**	**37%**	**65%**	**72%**	**2.3 (1.1-5)**	**<0.01**
Horner [81] *	22	100%	60%	100%	53%	2.2 (1.2-3.9)	
Horner [82] **	70	97%	29%	54%	91%	1.7 (0.8-3.7)	
Combined ALL	**173**	**83%**	**40%**	**63%**	**66%**	**1.8 (1.2-2.8)**	**<0.01**

* Included only brainstem strokes
** Included only bilateral strokes

Table 2.e.3 **Facial weakness** as a predictor of clinical detected dysphagia or aspiration during videofluoroscopy.
[Sensitivity (Sens), Specificity (Spec), Positive predictive value (+PV), Negative predictive value (-PV)]

Literature	n	Sens	Spec	+ PV	- PV	Relative risk (95%CI)	p
Gordon [66]	81*	80%	50%	53%	80%	2.7 (1.3-5.7)	
Kidd [93]	60	96%	31%	50%	92%	6 (0.9-40)	
Combined ALL	**141**	**88%**	**42%**	**52%**	**83%**	**3.1 (1.5-6.2)**	**<0.01**

* Information was not available in all study cases

Decreased or absent gag reflex is more sensitive and specific in identifying patients at risk of aspiration in brainstem strokes [81] than in bilateral hemispheric strokes [82] (Table 2.e.4). In single hemisphere strokes it appears to be of little [66] or no [84] significance. When all studies were combined, the sensitivity and specificity were 67% and 72%. The relative risk of having swallowing problems was 2.2 (95% confidence intervals 1.7-3) in patients with reduced or absent gag reflex. In a study of 140 healthy subjects across all adult age ranges, 37% had an absent gag reflex, with no apparent adverse functional consequences [46]. This, together with poor interobserver agreement in the assessment of gag reflex [46], may explain the low predictive value of the gag reflex in detecting patients at risk of aspiration.

The side of the hemispheric lesion is not associated with dysphagia [16, 66, 83, 93, 130, 137, 149, 155]. Although a high incidence of swallowing problems has been reported in brainstem [81] and bilateral strokes [82], it is not possible to combine these data to make an overall estimate of the true incidence of dysphagia.

2.f THE NATURAL COURSE OF DYSPHAGIA IN ACUTE STROKE

Table 2.f.1 shows the number of patients with swallowing problems on the first assessment and on consecutive follow-up assessments. Dysphagic patients, if they survive, recover their swallowing ability during the first weeks after the stroke [16, 66]. Of the 146 dysphagic patients who were assessed early after the stroke (combined data [16, 66]), only 4% were in hospital still suffering dysphagia 4-5 weeks later. A large

Table 2.e.4 Decreased or absent **gag reflex** as a predictor of clinical detected dysphagia or aspiration during videofluoroscopy.
[Sensitivity (Sens), Specificity (Spec), Positive predictive value (+PV), Negative predictive value (-PV)]

Literature	n	Sens	Spec	+ PV	- PV	Relative risk (95%CI)	p
Gordon [66]	81*	58%	90%	79%	75%	3.2 (2-5.3)	
Horner [83]	41*	60%	48%	52%	56%	1.2 (0.6-2.2)	
Horner [84]	21	55%	50%	55%	50%	1.1 (0.5-2.5)	
Linden [103]	15*	91%	50%	83%	67%	2.5 (0.5-12.6)	
Combined [66] [83] [84] [103]	**158**	**63%**	**72%**	**67%**	**68%**	**2.1 (1.5-3)**	**<0.01**
Horner [81] **	22	87%	57%	81%	50%	2.4 (0.8-7.7)	
Horner [82] ***	50	67%	50%	73%	70%	2.4 (1.2-4.5)	
Combined ALL	**230**	**67%**	**72%**	**70%**	**69%**	**2.2 (1.7-3)**	**<0.01**

* Information was not available in all study cases
** Included only brainstem strokes
*** Included only bilateral strokes

Table 2.f.1 The course of dysphagia in patients with swallowing problems on their first swallowing assessment.

	Delay between onset of stroke and swallowing assessment	Number of patients with swallowing problems after onset of stroke						Fatality: Number of cases
		On 1st assessment	7-9 days	14 days	30-40 days	6 months	At discharge	At the end of follow up
Barer [16]	≤48hours	105	25		4	0		60
Gordon [66]	≤13 days	41	6	3	at least 1			19
Gresham [69]	Not specified	53					40**	0
Teasell [149]	Mean of 39 days	42			(24)*			Not Known

* Assessed 40 days after the initial swallowing assessments.
** The mean length of stay was 50 days

proportion (49%) recovered safe swallowing, although 46% died in hospital.

The speed of resolution is more rapid in patients who had no initial impairment of consciousness, gaze deviation or sensory inattention [16]. Teasell [149] observed a trend towards a higher recovery rate for right hemisphere strokes [4 (44%) recovered out of 9 cases] compared with left hemisphere [1 (14%) out of 7 cases] and brainstem strokes [1 (9%) out of 11 cases], however these differences were not statistically significant.

2.g COMPLICATIONS OF DYSPHAGIA

2.g.1 Aspiration pneumonia

Entry of gastric juices, bacteria, or foreign matter into the lower respiratory tract may result in aspiration pneumonia. Diagnostic criteria have been hard to set and even more difficult to recognise. The cause of the pulmonary disease cannot be ascertained with certainty unless the episode of aspiration has been observed [32]. Therefore, historically, studies have been based on witnessed aspiration of large amounts of material which produce the classic clinical presentation of fever, leucocytosis, cough, sputum production, inspiratory crackles, and infiltrates in the lung on chest-X-ray [53]. Aspiration pneumonia is predominantly located in the right lobe and should be expected if aspiration is the causative factor [55].

The volume, character and frequency of the aspirate as well as the respiratory defense mechanisms [18, 55, 116] are, however, also decisive factors in the development of

aspiration pneumonia. The normal clearance and protective respiratory mechanisms are thought to be important for the prevention of aspiration pneumonia as normal adults may aspirate during their sleep without consequences [87].

Aspiration pneumonia is an important complication of stroke associated with significant morbidity and mortality [31, 75, 78]. It may prolong hospitalization, hamper the progress of rehabilitation, and is, together with pulmonary embolism, the most important cause of death after the first week of stroke [26, 58, 140, 156]. There is a strong association between swallowing dysfunction and aspiration pneumonia [108]. Respiratory protective mechanisms are also impaired in stroke patients, for instance the cough reflex may be depressed for up to four weeks from the onset of stroke [94]. This combined with a depressed swallowing reflex and prolonged pharyngeal transit [89] increases the risk of developing either a single or recurrent episode of aspiration pneumonia [114] in patients with or without concomitant disease [55].

The criteria used to diagnose chest infections in different studies can be seen in the foot of Table 2.g.1. The same table shows that patients with clinically detected dysphagia or aspiration during VFS had an increased risk of developing chest infection compared to those without swallowing problems. The relative risk was higher in the studies which used VFS than of those which used CSA, because they were carried out in a selected population of dysphagic patients. However, this difference was decreased by combining all available data.

Table 2.g.1 Clinically detected dysphagia and aspiration in the prediction of chest infection.
[Sensitivity (Sens), Specificity (Spec), Positive predictive value (+PV), Negative predictive value (-PV) and relative risk with 95% confident intervals (95%CI)]

	Dysphagia or aspiration detected by*:	n	% with chest infection	Sens	Spec	+PV	-PV	Relative risk (95%CI)
Gordon [66]	CSA	91	13%	67%	58%	19%	92%	2.4 (0.8-7.5)
Smithard [143]	CSA	117	25%	69%	55%	33%	84%	2.1 (1-4.2)
Combined [66] [143]	**CSA**	**208**	**20%**	**68%**	**56%**	**28%**	**88%**	**2.3 (1.3-4.2)**
Holas [80]	VFS	114	8%	89%	50%	13%	98%	7 (0.9-53.8)
Horner [83]	VFS	47	0%	---	---	---	---	---
Johnson [89]	VFS	60	48%	66%	71%	68%	69%	2.2 (1.2-3.9)
Schmidt [137]	VFS	59	10%	83%	60%	19%	97%	6.4 (0.8-51)
Combined [80] [83] [89] [137]	**VFS**	**280**	**16%**	**73%**	**55%**	**23%**	**91%**	**2.7 (1.5-5)**
Combined ALL		**488**	**17%**	**71%**	**55%**	**25%**	**99%**	**2.5 (1.6-3.8)**

* [Clinical Swallowing Assessment (CSA) or Videofluoroscopy (VFS)]

Diagnostic criteria for chest infections:

Gordon: Cough or fever and signs of chest infection on examination or in chest-X-ray film.

Smithard: Diagnosed and treated by the patient's medical tam

Schmidt: Three or more of the following items: Auscultatory findings on chest examination, productive cough, purulent sputum Gram's stain or pathogen isolated from sputum culture, PaO2 < 70 mmHg or 10 mmHg decrease from the patient's baseline, positive chest-X-ray film.

Johnson: Either segmental consolidation or infiltrate in the chest X-ray or when the physician identified episode of respiratory difficulty with segmental moist rales on chest auscultation plus two of the following items: fever, hypoxia, increased white cell blood count.

Holas: Three or more of the following items: Fever, decreased PaO2, purulent sputum Gram's stain or pathogen isolated from sputum culture, dehydration.

Horner: Not specified

Pooling of the valleculae and the piriform fossae is associated with increased relative risk (2.5, $p < 0.01$ and 2.3, $p = 0.016$ respectively) of developing a chest infection as it was estimated from the data in Johnson [89].

2.g.2 Dehydration

Dehydration after an acute stroke may be a theoretical complication, but there is little evidence to support the theory. Gordon [66] found a non significant increase of packed cell volume in 9 (27%) of 33 patients with dysphagia compared with 4 (13%) out of 31 patients with normal swallowing. However, larger studies [16, 143] did not support these findings. On the other hand, patients may by artificially hydrated with parenteral fluids and it also has been shown that in some cases overhydration occurs because of arginine vasopressin release [117]. Furthermore, excess morbidity and mortality attributable to a small degree of haemoconcentration is very low and not preventable by haemodilution [118, 135].

2.g.3 Malnutrition

Nutritional status influences both length of stay in hospital and outcome [4, 25, 139]. In common with other pathologies [23, 54], nutritional status deteriorates after stroke [6], but this was not examined in relation to dysphagia. Smithard [143] showed recently that nutritional indices of patients with dysphagia deteriorate significantly more than of those without swallowing problems, suggesting a relation with nutritional support rather than changes due to stroke, for example the increase in metabolic rate with cerebral

haemorrhage [151].

2.h DYSPHAGIA AND OUTCOME

Dysphagia is associated with adverse outcome. Table 2.h.1 shows that in studies [16, 66, 143, 159] which examined consecutive patients early after stroke mortality is higher in patients with dysphagia compared to those without swallowing problems. This association was consistently significant. Overall, of the 388 patients who suffered swallowing problems (combined data) 44% died, compared to 15% of the 601 patients without dysphagia.

Whether dysphagia has an independent effect on outcome was studied in a multivariate analysis model by Barer [16], who showed that after allowing for stroke severity, dysphagia was still independently associated with poor outcome. Although this could explain only 4% of the variance.

Dysphagia also appears to be associated with increased length of stay in hospital [6, 143]. Smithhard [143] showed that patients with swallowing problems stay a (geometric) mean of 20 days longer in hospital compared to those without dysphagia, although this appeared to be confounded by the effects of stroke severity.

Table 2.h.1 Relative risk of dying and fatality rates in patients with clinically diagnosed dysphagia.
(Patient selection: consecutive acute stroke patients)

	Follow up after stroke onset at	Number of deaths in patients with dysphagia (%)	Number of deaths in patients without dysphagia (%)	Relative Risk (95% CI)	p
Barer [16]	6 months	60/105 (57%)	38/250 (15%)	3.8 (2.7-5.3)	
Gordon [66]	6 weeks	19/41 (46%)	11/50 (22%)	2.1 (1.4-3.9)	
Smithhard [143]	6 months	18/49 (37%)	3/50 (6%)	6.1 (1.9-19.5)	
Wade [159]*	6 months	72/193 (37%)	36/251 (14%)	2.6 (1.8-3.7)	
Combine ALL		**169/388 (44%)**	**88/601 (15%)**	**3.0 (2.4-3.7)**	**<0.01**

* 8 cases had not been followed up and were excluded from the analysis.

2.i MANAGEMENT OF DYSPHAGIA

Smith and Dodd [142] suggested in their editorial that early detection of dysphagia in stroke patients, appropriate management and treatment may prevent aspiration and improve functional outcome. The management of dysphagia requires a coordinated approach by a multidisciplinary team [128] involving both the patient and the family [101].

Intravenous fluids are usually given during the acute phases of stroke to hydrate patients who are on restricted oral feeding. Nasogastric tube [120] feeding has been used for many years to provide adequate nutritional support both acutely and chronically, although it is not well tolerated [61]. Recently, percutaneous endoscopic gastrostomy [123] has been used for long term feeding as it is thought to be "superior" to nasogastric tube feeding [91, 119, 132].

Enteral feeding does not always protect against the development of aspiration pneumonia [35, 36, 89]. This may be related to aspiration of stomach contents [119] or aspiration of saliva [105]. It has also been suggested that enteral feeding may increase the risk of aspiration pneumonia [33].

The literature provides little evidence on what methods, if any, are routinely used to detect swallowing problems early after a stroke and whether the necessary precautions are taken to protect stroke patients at risk of aspiration.

In a retrospective study Gresham [69] examined one year's hospital records (n= 160) of

stroke admissions. Of the 98 patients who were referred for speech and language therapy assessment, 53 (54%) were found to have swallowing problems. However, 30 (57%) out of these 53 patients with dysphagia were on inappropriate oral diet. Of the 23 patients who were on enteral feeding, half were found to be able to manage oral feeding in some form, whereas 23% of the 17 patients on thin fluids were judged to be at risk of aspiration.

2.j CONCLUSIONS

Most of the dysphagia studies have been carried out late after a stroke, in selected populations, using VFS to detect aspiration. By contrast, only few studies examined dysphagia in the early stages after a stroke. The use of VFS early after stroke is, however, problematic, as many patients who are at high risk of aspiration, are not well enough to maintain the positioning required for this procedure. Clinical swallowing assessments have been used to detect patients at risk of aspiration, although none of these have been adequately validated. Fibreoptic nasoendoscopy has been developed as an alternative technique to VFS for the detection of aspiration, but so far, it has not been evaluated in stroke populations.

Dysphagia is related with increased morbidity and mortality, however, the knowledge of natural history and course of dysphagia is insufficient for taking "evidence based" management decisions. Furthermore, there is no evidence in the literature, on the current methods used for the detection and management of dysphagia early after stroke, although more information appears to be available for the later stages.

Chapter 3

METHODS

3.a PATIENT SELECTION AND STROKE REGISTER

The study was carried out in two Liverpool teaching hospitals, the Royal Liverpool University Hospital (RLUH) from June 1991 to December 1993 and Broadgreen Hospital (BGH) between November 1992 and December 1993.

In each case a register was kept of all adults admitted with acute stroke (according to WHO criteria [76]). The accuracy of the stroke register was maintained by examining the Accident and Emergency (A&E) Department admission records. All patients admitted with the provisional diagnosis of "stroke", "possible stroke", "old stroke", "transient ischaemic attack (TIA)", "? neurological signs" and "collapse" were examined on the wards by a member of the stroke team to confirm or refute the diagnosis of stroke. In addition, senior ward staff in each of the acute General and Geriatric Medicine wards were contacted weekly to find out whether any stroke patients had been omitted from the register. The medical records of patients who died in A&E were also checked.

The diagnosis of stroke was based on clinical signs, and diagnostic brain imaging was only requested by the admitting medical team. Patients were excluded from the register if subsequent investigation revealed another cause of the presenting "stroke syndrome" (eg. epilepsy, brain tumour, subdural haematoma, etc). Patients with neurological signs

lasting less than 24 hours or with subarachnoid haemorrhages without focal signs were also excluded. Patients re-admitted with another stroke during the study period were re-registered as a new case episode (see Chapter 6.f.1).

3.b DEMOGRAPHIC DATA AND PRE-STROKE STATUS

Demographic data were collected in all cases. Information on patients' functional status about one month before the current stroke was collected by using the modified "Rankin" (Oxford Handicap Scale) [9, 127]. This is a simple, reliable [154], six point scale (from 0 to 5), which measures to some extent impairment (symptoms), to some extent disability and to a lesser extent handicap (Fig. 3.b.1). Three "pre-stroke disability" categories were then derived: "none" for scores 0-1, "mild" for scores 2-3 and "severe" for scores 4-5.

3.c CLINICAL ASSESSMENTS

3.c.1 Neurological Assessments

The progress of each patient was measured by recording changes in the individual neurological items listed in Fig 3.c.1. Each item was rated on an ordinal scale, so that changes between assessments could be easily detected. The neurological assessments used in this study were a modification of those used in previous studies [11]. Many of the definitions were close to those used in the National Institute of Health (NIH) stroke scale [30]. In addition ,"hand power" and "gait" were taken from the Scandinavian

Fig 3.b.1 **"RANKIN" (OXFORD HANDICAP SCALE)**

Score	**Definition**
0	Well, no symptoms
1	Minor symptoms not affecting lifestyle
2	Minor handicap, but independent in selfcare
3	Moderate handicap, but needs a little help with ADL*
4	Needs a lot of help with ADL
5	Needs constant attention day and night

*(Activities of Daily Living)

Fig 3.c.1 **NEUROLOGICAL ASSESSMENT**

CONSCIOUS LEVEL 1= Alert, 2= Drowsy but rousable responding to speech
3= Some response but no eye opening to speech
4= Responding to pain only

GRADE OF SPEECH 1= Normal communication, 2= Limited conversation
3= Little speech but understands simple commands
4= Little or no verbal communication

QUALITY OF SPEECH 1= Normal, 2= Dysarthria, 3= Dysphasia, 4= Both

RESPONSE TO COMMAND (Raise your good hand=A; Touch your opposite ear=B
1= Does A+B, 2= Does A, 3= Neither

ORIENTATION (How long have you been here**? Name of this place? Day of the week?)
1= All answers correct, 2= Only one wrong,
3= Two wrong, 4= All wrong
(**Allow no error on day 1; +/- 1 day after 1 week; +/- 2 days after 2 weeks;)

CONJUGATE GAZE PARESIS 1= Normal, 2= Will not look towards affected side
3= Eyes deviated from affected side

VISUAL ATTENTION /FIELDS 1= Normal, 2= Extinction, 3= Ignores one side (or hemianopia)

SENSATION 1= Normal, 2= Extinction, 3= Ignores one side(or hemianesthesia)

HEAD AND TRUNK CONTROL 1= Normal sitting balance, 2= Sitting balance but not maintained
3= Some head control but not sitting balance, 4= No head control

FACIAL MOVEMENTS 1= Normal, 2= Impaired

POWER IN AFFECTED HAND 1= Normal, 2= Reduced strength
3= Some movement (fingertips do not reach palm), 4= No movement

POWER IN AFFECTED ARM 1= Normal, 2= Weak but moves against resistance,
3= Moves against gravity only, 4= Unable to lift limb, 5= No movement

POWER IN AFFECTED LEG 1= Normal, 2= Weak but moves against resistance,
3= Moves against gravity only, 4= Unable to lift limb, 5= No movement

GAIT 1= Walks 5m without aids, 2= Walks with aids,
3= Walks with help, 4= Sits without support
5= Bedridden/wheelchair

CEREBELLAR SIGNS 1= No, 2= Yes

BRAIN STEM SIGNS 1= No, 2= Yes

SIDE AFFECTED(by new stroke) 1= Right, 2= Left, 3= Both, 4= Neither

SIDE OLD NEURO SIGNS 0= None, 1= Right, 2= Left, 3= Both, 4= Cerebellar; 6= Brain stem

Stroke Scale (SSS). In most cases, the signs were analysed individually, but for some purposes the total SSS score was used as an indicator of stroke severity.

The SSS is reliable [104], and has been used in acute stroke trials [134, 135]. It consists of 9 items (Fig 3.c.2) scoring between 0 to 12 with a maximum score of 58. The ratings of the appropriate neurological items from this study were recoded to the SSS rating system so that the SSS score could be derived. In those cases, where one or two of the neurological items could not be assessed, the total measured score was adjusted by multiplying by $58/MAX_{Items}$ (where MAX_{Items} is the maximum possible total on those items that could be assessed). No case had more than two "non assessable" items, however.

The SSS score has also been used to define three categories of stroke severity. Patients who scored 0-18 were considered to have a "very severe stroke", from 19 to 32 a "severe stroke", from 33 to 44 a "moderate stroke" and from 44 to 58 a "mild stroke". (These SSS groups differ from those used in a previous study [136]). The categories were only used for some analysis; in multivariate analysis the actual scores were used.

Neurological assessments were carried out on days 1, 3, 7, 14 and 28 from onset of stroke (or until discharge from hospital if this was sooner) at RLUH by the author (JE) and at BGH by a colleague (PG), who was assisting the study.

The neurological assessment on day 1 was used to classify patients into 4 stroke subtypes according to OCSP (Oxfordshire Community Stroke Project) classification [8]

Fig 3.c.2 **SCANDINAVIAN STROKE SCALE (SSS)**

FUNCTION	Score	Definition
CONSCIOUS LEVEL	2	Reacts to verbal command to full consciousness
	4	Somnolent, but cannot be fully awakened
	6	Fully alert
EYE MOVEMENTS	0	Conjugate eye deviation at rest
	2	Lateral gaze paresis
	4	Normal conjugate eye movements
ARM, MOTOR POWER	0	Paralysis
	2	Can move, but not against gravity
	4	Raises arm
	5	Raises arm with reduced strength with flexion at elbow
	6	Raises arm with normal strength
HAND, MOTOR POWER	0	Paralysis
	2	Some movement, fingertips do not reach palm
	4	Reduced strength in full range
	6	Normal strength
LEG, MOTOR POWER	0	Paralysis
	2	Can move, but not against gravity
	4	Raises leg with flexion at knee
	5	Raises straight leg with reduced strength
	6	Normal strength
ORIENTATION	0	Completely disorientated
	2	Correct for 1/3 (time, place, person)
	4	Correct for 2/3
	6	Correct for all three
SPEECH		
	0	Only yes/no or less
	3	More than yes/no, but no longer sentences
	6	Limited vocabulary or incoherent speech
	10	No aphasia
FACIAL PALSY	0	Present
	2	Non/dubious
GAIT	0	Bedridden/wheelchair
	3	Sits without support
	6	Walks with help
	9	Walks with aids
	12	Walks 5m without aids

definitions [Total Anterior Circulation Syndrome (TACS), Partial Anterior Circulation Syndrome (PACS), POsterior Circulation Syndrome (POCS), LACunar Syndrome (LACS)]. Patients with residual neurological signs from a previous stroke, those in stupor or coma on admission to hospital, and those in whom key neurological items were not assessable, were put into the "unclassified" category.

3.c.2 Standardised Swallowing Assessment (SSA)

The development and characteristics of the SSA are examined in detail in Chapter 4.

In outline, the SSA (Fig 3.c.3) consists of a 3-stage process:

Stage I.

A preliminary assessment of conscious level and postural control is carried out, together with an evaluation of other general factors likely to affect swallowing safety. These include lip and tongue movements, gag reflex, voluntary cough and voice quality. Only those patients sufficiently alert, able to hold their heads up, and being considered for oral feeding, are assessed further.

Stage II.

Patients are then sat up and given 3 teaspoonfuls of water. After each teaspoonful careful observations are made of laryngeal movement, signs of pooling of fluid around the laryngeal opening ("wet" or "gurgly" voice), or signs of aspiration (coughing, choking, respiratory distress). As a result of these observations the decision is taken whether it is safe to proceed to Stage III.

Fig 3.c.3 **STANDARDISED SWALLOWING ASSESSMENT (SSA)**

STAGE I

CONSCIOUS LEVEL	1= Alert, 2= Drowsy but rousable responding to speech 3= Some response but no eye opening to speech 4= Responding to pain only
HEAD AND TRUNK CONTROL	1= Normal sitting balance, 2= Sitting balance but not maintained 3= Some head control but not sitting balance, 4= No head control
BREATHING PATTERN	1= Normal, 2= Abnormal
LIPS CLOSURE	1= Normal, 2= Abnormal
TONGUE MOVEMENT	1= Normal, 2= Abnormal
PALATE MOVEMENT	1= Symmetrical, 2= Asymmetrical, 3= Minimal/Absent
WEAK VOICE	1= Normal, 2= Weak, 3= Absent
GAG REFLEX	1= Present, 2= Decreased, 3= Absent
VOLUNTARY COUGH	1= Normal, 2= Weak, 3= Absent

STAGE II

WATER DRIBBLING	1= None/once, 2= >once
LARYNGEAL MOVEMENT	1= Yes, 2= No
REPEATED LARYNGEAL MOVEMENT	1= None/once, 2= >once
COUGH STAGE II	1= None/once, 2= >once
CHOKING STAGE II	1= No, 2= Yes
VOICE QUALITY STAGE II	1= Normal, 2= Wet/Gurgly voice, 3= Absent

STAGE III

COMPLETE ASSESSMENT	1= Yes, 2= No
NUMBER OF SIPS**	number
TIME TAKEN TO COMPLETE	seconds
COUGH STAGE III	1= None/once, 2= >once
CHOKING STAGE III	1= No, 2= Yes
VOICE QUALITY STAGE III	1= Normal, 2= Wet/Gurgly voice, 3= Absent
SWALLOWING SAFETY	1= Safe swallowing, 2= Possibly unsafe swallowing, 3= Definitely unsafe

Stage III.

The third stage involves drinking 60 mls of water from a glass. Observations are made for the same signs as in stage II, the speed of drinking and whether the patient is able to finish the glass. In addition to recording individual signs, an overall final judgement is made as to whether the patient's swallowing is "safe", "possibly unsafe" or "definitely unsafe".

The SSA was performed on the same days as the neurological assessment, but discontinued following two consecutive normal swallowing assessments. However, if the patient subsequently suffered from an obvious neurological deterioration, swallowing assessments were resumed.

3.d OUTCOME ASSESSMENTS

The following simple and reliable measures, and proxy measures, of outcome, were assessed:

Length of stay in hospital (LOS) and Fatality rate

The LOS was calculated as the number of days spent in hospital (until discharge or death), so including acute care and rehabilitation. Only deaths in hospital were included in the fatality rate.

Discharge destination and fatality rate

The possible categories of discharge destination are shown in Fig 3.d.1.

Incidence of chest infection

To avoid bias, only the occurrence of chest infections, diagnosed (clearly documented and/or treated) by the admitting medical team, was recorded by the investigator carrying out the clinical assessments. When antibiotics were given, but the documentation was uncertain (eg "?chest infection") it was considered as a "possible chest infection", whereas when a specific diagnosis was made, it was recorded as an episode of "definite chest infection".

Functional outcome

The patient's functional status was measured using the Barthel ADL Index [107] in its modified form [39, 68]. The Barthel ADL Index comprises 10 basic daily living activities (Fig. 3.d.2). The score on each item ranges between 0 and 3 points, giving a maximum total Barthel score of 20. Scores are based on what patients actually do do, rather than on what it is thought they might be able to do [39, 68].

Assessments of functional status at discharge were carried out by other investigators (not involved in the dysphagia study), who informally interviewed the ward staff within 48 hours of the patient's discharge from hospital.

Fig 3.d.1

DISCHARGE DESTINATION

Private address alone

Private address not alone

Residential home

Nursing home

Long stay hospital

Other hospital

Fig 3.d.2 **THE MODIFIED BARTHEL INDEX**

Function	Score	Description
BOWELS	0	Incontinent (or needs to be given enema)
	1	Occasional accident (once a week)
	2	Continent
BLADDER	0	Incontinent, or catheterised and unable to manage
	1	Occasional accident (max. once per 24 hours)
	2	Continent (for more than seven days)
GROOMING	0	Needs help with personal care: face, hair, teeth, shaving
	1	Independent (implements provided)
TOILET USE	0	Dependent
	1	Needs some help but can do something alone
	2	Independent (on and off, wiping, dressing)
FEEDING	0	Unable
	1	Needs help in cutting, spreading butter etc.
	2	Independent (food provided within reach)
TRANSFERS	0	Unable - no sitting balance
(bed/chair)	1	Major help (physical, one or two people), can sit
	2	Minor help (verbal or physical)
	3	Independent
MOBILITY	0	Immobile
	1	Wheelchair independent, including corners etc.
	2	Walks with help of one person (verbal or physical)
	3	Independent
DRESSING	0	Dependent
	1	Needs help but can do about half unaided
	2	Independent (including buttons, zips, laces etc.)
STAIRS	0	Unable
	1	Needs help (verbal, physical, carrying aid)
	2	Independent up and down
BATHING	0	Dependent
	1	Independent (Bath: must get in and out unsupervised and wash self. Shower: unsupervised/unaided)

3.e ORGANISATION OF THE STUDY

The author (JE) participated in the conception and development of the SSA as a collaborator of the Merseyside and North West Stroke Dysphagia Group. Initially this involved Liverpool Royal and South Manchester University Hospitals, but the collaboration was later extended to include Leighton Hospital, Crewe and Clattebridge Hospital, Wirral.

Interobserver studies and formal studies comparing the SSA with videofluoroscopy were carried out at South Manchester University Hospitals. JE participated at these interobserver studies by carrying out swallowing assessments.

JE set up this study in Liverpool and carried out virtually all the patient assessments at RLUH and some at BGH, analysed the data, disseminated the results and coordinated the multidisciplinary discussions before implementing changes in clinical practice. The contribution of the other research doctor (PG), who helped with the dysphagia study at BGH, was also organised by the author.

Chapter 4

DEVELOPMENT AND VALIDATION

OF THE STANDARDISED SWALLOWING ASSESSMENT (SSA)

4.a DEVELOPMENT OF THE SSA

At the time that this study was conceived, scientific interest in dysphagia after stroke was increasing, and research based evidence was insufficient for guiding management decisions. For instance in South Manchester University Hospital all acute stroke patients were kept "nil by mouth" until they were assessed by speech therapists, whereas in both Liverpool Royal and Broadgreen Hospitals there was no coordinated policy on dysphagia management.

Doctors and speech and language therapists (SLTs) of the Merseyside and North West Stroke Dysphagia Collaboration perceived the need for an adequately validated standardised swallowing assessment (SSA), which could be carried out early after stroke. It was agreed that in most British hospitals it is not feasible for stroke patients to have swallowing assessments by a SLT within hours of their admission to hospital. Therefore, the SSA was designed to be a simple and quick bedside test that might be used by non-specialists as an initial screening test for dysphagia.

Studies by Gordon [66] in 1987 and Barer [16] in 1989 had indicated that administration of small amounts of water provided useful information on dysphagia, and thus could be

used for screening. More complex swallowing assessments (eg using meals of different consistencies [146]) are more appropriate for feeding management.

The literature, together with the experience of the SLT's, formed the basis for the SSA. By the spring of 1991, the SSA had acquired its present format of a 3-stage process, already described in Chapter 3.c.2 and illustrated in Fig 3.c.3.

Safety of patients during the assessment was the prime concern. The SSA was designed to be used soon after the stroke, before any other oral feeding, therefore the assessor was advised to discontinue the procedure at any stage (even before giving the first teaspoonful of water), if it was felt unsafe to continue.

All the main predictors of dysphagia known at that time were included in the SSA. Pharyngeal sensation was not included, as it was only suggested as a good predictor of aspiration at a later date (Kidd [93] 1993). Only those signs likely to be directly related to swallowing were included, so signs of stroke severity, such as gaze paresis, were also omitted, although they were assessed as part of the neurological examination during this study.

4.b CHARACTERISTICS OF THE SSA

The relation between each SSA item and the overall judgement of the assessor ("safe" or "unsafe" swallowing) was examined in 564 assessments carried out on day 1. The

overall judgment was not explicitly based on these signs, as stated above.

Not all SSA items could be assessed in every case, as can been seen from the different denominators in Table 4.b.1. For instance the palate movements were not assessable in 20% of the cases, and voluntary cough in 17% of the cases, as these two items require greater patient comprehension and cooperation than others.

Of all patients assessed by the SSA, 25% were not considered safe enough to proceed from stage II to stage III and 14% attempted to drink from a glass, although they did not complete the assessment.

Abnormalities in breathing pattern, lip closure, absent laryngeal movement or choking, although strongly correlated to the overall safety assessment, occurred rarely and thus had low sensitivity.

Inability to finish a glass of water was strongly associated with the overall safety assessment, but this is because the investigator discontinued the assessment at this stage, if the swallowing was felt to be unsafe. Coughing during swallowing appeared to be a key contributor to the investigator's overall judgement. For example, patients who coughed while drinking water from a glass had 18-fold increased risk of being rated "unsafe" according to the SSA. Voluntary cough was also strongly correlated to swallowing safety, though this is unlikely to have directly affected the assessor's overall judgement in the same way.

Table 4.b.1 Relation of each SSA item with the overall swallowing safety.
(Patients "not assessable" by SSA on day 1 are excluded)

	Abnormal n (%)	Sensitivity	Specificity	Relative risk* (95% CI)
STAGE I				
Conscious level	77/555 (14%)	28%	94%	2.4 (2-2.9)
Head control	200/523 (38%)	66%	75%	3.1 (2.4-4)
Breathing pattern	19/556 (3%)	9%	99%	2.7 (2.2-3.3)
Lips closure	32/563 (6%)	14%	99%	2.7 (2.2-3.2)
Tongue movement	68/504 (13%)	34%	96%	3.7 (2.7-4)
Palate movement	57/453 (13%)	29%	94%	2.8 (2.1-3.6)
Weak voice	85/498 (17%)	42%	94%	3.5 (2.8-4.3)
Gag reflex	232/492 (47%)	66%	62%	2.2 (1.7-2.9)
Voluntary cough	88/468 (19%)	49%	93%	4.2 (3.3-5.4)
STAGE II				
Water dribbling	112/528 (21%)	48%	91%	3.5 (2.8-4.3)
Laryngeal movement	44/549 (8%)	22%	99%	3.3 (2.8-3.8)
Repeated laryngeal movement	52/513 (10%)	28%	98%	3.5 (2.8-4.3)
Cough stage II	73/515 (14%)	46%	99%	5.1 (4.2-6.2)
Choking stage II	24/520 (5%)	15%	100%	3.7 (3.2-4.2)
Voice quality stage II	41/473 (9%)	28%	99%	4.3 (3.4-5.3)
STAGE III				
Assessment not completed	221/563 (39%)	84%	85%	8.1 (5.8-11.4)
Number of sips**	25/341 (7%)	18%	94%	2.8 (1.3-6.2)
Time taken to complete***	78/340 (23%)	56%	81%	4.3 (2.3-8.3)
Cough stage III	62/421 (15%)	76%	97%	18 (11.2-29)
Choking stage III	20/422 (5%)	24%	99%	6.3 (4.7-8.6)
Voice quality stage III	19/414 (5%)	23%	99%	6.1 (4.3-8.6)

Different denominators because SSA items were not always assessable

* Indicates the risk of being rated "unsafe" according to the overall SSA
** Abnormal for more than 6 sips of water
*** Abnormal for more than 15 seconds

Univariate analysis, however, does not allow for the intercorrelation between items. Thus, a multiple logistic regression analysis (LRA) was carried out to identify which items made the greatest independent contribution to the overall judgement of swallowing safety.

The data file was randomly divided in three roughly equal parts (subsets). In each of the three subsets LRA was performed separately for each of the three SSA stages. Items which were consistently associated with the overall swallowing safety, were identified.

Of the SSA stage I items, only voluntary cough was significantly associated ($p < 0.01$) with the overall SSA and this in all three subsets. On SSA stage II, water dribbling, repeated laryngeal movement and coughing were significantly associated in 2 out of the 3 subsets, and finally, on stage III, coughing was significantly associated in all 3 subsets, whereas choking and voice quality were significant in only 1 subset.

The analysis was then repeated with the "not assessable" items assigned to the "worst" score. The results confirmed the above findings.

Thus, the signs contributing most to the overall swallowing safety are voluntary cough, dribbling water, repeated laryngeal movements, and coughing. These items should, therefore, be retained in any subsequent version of the SSA.

4.c VALIDITY AND RELIABILITY OF CLINICAL ASSESSMENTS

In interpreting the results of any statistical analysis, it is important to ensure the validity and reliability of the assessments used.

Validity reflects the degree to which a test measures what it is intended to measure and it can be said to affect the accuracy of the assessment. Three types of validity can be distinguished: content, criterion and construct validity [92].

Content validity involves a non-statistical, subjective evaluation of the extent to which a test or measure covers the issues of interest. Criterion validity examines the relation of the results of a test to a superior criterion or a "gold standard", whereas construct validity indicates to what extent the results behave in the way expected of the underlying construct. Thus, there should be a high correlation with other measures within the same domain (convergent validity), and a low correlation with tests intended to assess different domains (discriminant validity). Some authors describe a fourth type, the "clinical validity" [77], which examines whether the instrument is able to distinguish between patients with different diagnoses or between patients with different degree of disease severity, and whether it registers changes within patients as a result of treatment. Others consider this latter issue of responsiveness to change to be distinct from validity [71].

Reliability can be said to affect the precision of the measurement. Two types of reliability can be evaluated: the internal consistency (homogeneity) and the stability.

Internal consistency refers to the coherence of a scale and reflects the extent to which the items measure a common entity [40]. The stability can be assessed in terms of interobserver and intra-observer reliability. The former refers to the agreement between different independent raters assessing a clinical sign or phenomenon with the same instrument at the same time. The latter usually refers to "test-retest" reliability, in which the same person performs the assessment on two or more occasions, using the same instrument. In practice this usually requires the use of videorecording to avoid problems due to changes in the actual status of the patient.

The comparison of the SSA with the conventional "gold standard", the videofluoroscopy (VFS), was studied in a selected population at RLUH and the results are reported in Chapter 5.

Even VFS cannot be regarded as the ultimate criterion of swallowing safety. Another way of assessing this criterion indirectly is simply to measure outcome in an observational study. The SSA was related to outcome and the results are described in Chapter 7. Construct validity was assessed by relating complication rates and overall outcome to the severity of swallowing impairment found on SSA. Limited interobserver studies were performed during 1991, but more extensive testing was done in 1995. The later interobserver studies are described in Appendix A. Test-retest reliability studies using videorecordings have not been carried out so far.

This chapter considers the content validity of the SSA and describes the first interobserver study.

4.d CONTENT VALIDITY OF THE SSA

The items of the SSA were agreed by representatives of the main professional groups involved in the management of dysphagia in Britain, including speech and language therapists, doctors and nurses from three different hospitals (in Liverpool, Manchester, Crewe). All the main areas of interest were covered, though only water, rather than thickened fluids or solids were used. This is because the SSA was designed as a screening assessment for dysphagia in acute stroke, rather than as a guide to specific management of feeding.

Some items were included to improve safety (eg head control), others because they were either believed or had shown to be associated with dysphagia or aspiration. For instance, tongue movements were assessed in stage I of the SSA as they were thought to be an important part of the oral phase of swallowing. Combined data (n= 140) from two studies [66, 93] had also shown that patients with abnormal lingual motility had a 2.2-fold increased risk (95%CI 1.5-3.3) of aspirating during VFS.

Similarly, combined data of three studies [66, 83, 84] on 142 stroke patients, had shown that abnormalities of voluntary cough were associated with a doubling of the relative risk of aspiration during VFS (95%CI 1.3-2.8). By contrast, the gag reflex was included because it appeared to be commonly used as a substitute for formal clinical swallowing assessment. The present study, therefore, provided further information to evaluate the usefulness of the gag reflex in swallowing management.

Absence of laryngeal movement was included in stage II of the SSA because it is an obvious sign of severe abnormality. A change in voice quality (wet or gurgly voice) was included as it indicates pooling around the vocal cords, and it has already been used in other studies [49, 84, 149]. Although there is little published data, it is reasonable to assume that coughing or choking while drinking indicates penetration of material into the larynx itself.

4.e INTEROBSERVER RELIABILITY STUDIES

4.e.1 Methods

This study involved the author and a junior doctor, who had not received special training in the use of the SSA. During a period of 9 weeks, 49 stroke patients were assessed by both observers, without conferring, within 24 hours of each other, at Broadgreen Hospital.

Agreement between investigators was measured using the Cohen's Kappa (K) [37] and the quadratically weighted Kappa (K_2) [38]. The K measures the difference between the observed proportion of cases in which the investigators agreed and the proportion of agreement expected by chance. It has been suggested that values of < 0.2 indicate poor agreement; 0.2 to 0.4 fair agreement; 0.41 to 0.6 moderate agreement; 0.61 to 0.8 good agreement; and 0.81 to 1 very good agreement [28, 95].

K_2 takes into account not only the frequency but the size of interobserver differences.

These differences are squared and the totals rescaled to produce a quadratically weighted percentage disagreement. For interval measures, K_2 is equivalent to the reliability coefficient. K_2 was not calculated in those cases where a score of "not assessable" had been given.

4.e.2 Results

For many items the proportion of expected agreement (Pexp) between investigators was high because of the low prevalence of the observed abnormalities (Table 4.e.1). Pexp was over 98% for breathing pattern and for choking in stage III, so the K value indicated only chance agreement. Good agreement beyond chance was observed for lip closure, choking during stage II and for completion of the whole SSA. Agreement between investigators for the overall assessment (ie safe/possibly unsafe/definitely unsafe swallowing) was only fair ($K = 0.25$), but improved somewhat ($K_2 = 0.4$) when quadratic weighting was used.

4.e.3 Discussion

Initially these findings did not seem encouraging for extending the use of the SSA to other professionals.

The junior doctor participating in this study had no experience in swallowing assessments. This, together with the lack of clear guidelines on how to perform the SSA, may largely explain these results. Furthermore, the investigators carried out

Table 4.e.1 SSA: Interobserver agreement between two investigators

[Kappa (K) with 95% confidence intervals (95% CI), weighted Kappa (K_2), and proportions of observed (Pobs) and expected agreement (Pexp) are illustrated in the table].

	K (95%CI)	K_2	Pobs	Pexp
STAGE I				
Conscious level*	0.48 (-0.31, 0.65)	0.8	92%	84%
Head control*	0.26 (0.06, 0.46)	0.61	74%	65%
Breathing pattern	0	0	98%	98%
Lips closure	0.66 (0.39, 0.39)	0.66	98%	94%
Tongue movement	0.05 (-0.18, 0.28)	---	76%	75%
Palate movement	0.39 (0.21, 0.57)	---	76%	61%
Weak voice	0.1 (-0.1, 0.3)	---	70%	66%
Gag reflex	0.37 (0.28, 0.46)	---	59%	35%
Voluntary cough	0.48 (0.29, 0.66)	---	74%	50%
STAGE II				
Water Dribbling	0.35 (0.12, 0.58)	0.35	86%	79%
Laryngeal movement	0.54 (0.25, 0.83)	0.54	93%	86%
Repeated laryngeal movement	0	---	93%	93%
Cough stage II	0.22 (-0.08, 0.52)	0.22	88%	85%
Choking stage II	0.65 (0.38, 0.92)	0.65	95%	87%
Voice quality stage II	0.12 (-0.12, 0.37)	---	85%	82%
STAGE III				
Complete assessment	0.67 (0.37, 0.97)	0.67	86%	58%
Number of sips**	0.51 (0.13, 0.89)	0.51	88%	77%
Time taken to complete***	0.38 (0.13, 0.63)	0.5	65%	44%
Cough stage III	0.15 (-0.18, 0.48)	0.15	83%	80%
Choking stage III	0	0	100%	100%
Voice quality stage III	-0.04 (-0.35, 0.27)	-0.04	91%	92%
Swallowing safety	0.25 (0.04, 0.5)	0.4	67%	56%

* Three patients in stupor were not assessed further

** Classified as ≤6 and >6

*** Classified as ≤15, 16-30 and >30 seconds

separate assessments, so that the actual findings could have altered in the interval.

The author (JE) participated in another interobserver study organised by a colleague (DS) in Manchester, who had experience in using the same SSA in his own dysphagia studies. Stroke patients (n= 65) were assessed by the two investigators within 32 hours of each other. The overall agreement on swallowing safety was better, but still only moderate (K= 0.5, 95%CI 0.26-0.73) [144].

Neither the Liverpool nor the Manchester interobserver studies were preceded by training or agreement on the precise definitions of the SSA items.

4.f OTHER ASSESSMENTS OF RELIABILITY AND VALIDITY

Yet, another interobserver study, carried out by nurses after a period of theoretical and practical training, was organised by JE in 1995. This study is described in the Appendix A.

Colleagues from the Merseyside and Northwest Dysphagia Group compared the SSA with VFS in a study carried out in Manchester (Smithard et al [144]). A total of 149 consecutive patients, admitted within 24 hours from stroke onset, were included into the study. Of these, 28 (19%) were not well enough to be assessed by the SSA. VFS was carried out within 3 days from stroke onset in 98 out of the 121 patients, who had been assessed by the SSA. The results were shown in Table 2.c.3.

The relation of dysphagia detected by the SSA to the complications and overall outcome is examined in chapter 7.

Chapter 5

COMPARISON OF SSA WITH INSTRUMENTAL ASSESSMENTS

5.a AIMS and METHODS

5.a.1 Aims

Instrumental assessments of dysphagia, such as videofluoroscopy and fibreoptic nasendoscopy, were not widely available at the time of this study, though today they appear to be more readily accessible. It is, therefore, crucial to establish the role of any clinical assessment in relation to these assessments.

The obvious approach would be to compare the standardised swallowing assessment (SSA) or any other assessment with a "gold standard". Videofluoroscopy (VFS) appears to be highly sensitive in detecting aspiration, but it is not clear whether occasional aspiration of small amounts is of any clinical significance. Therefore, for this study, the SSA and fibreoptic nasendoscopy were not only compared with VFS, but the value of all three assessments in predicting complications such as chest infection was also explored.

As well as defining the risk of aspiration for materials of different consistencies, instrumental investigations also provide additional information on pooling within the pyriform fossae, and on the effectiveness of protective mechanisms. The value of this information in predicting chest infection was also studied.

In this study, fibreoptic nasendoscopy is referred to as "milk nasendoscopy" because the test involved observing the patient while drinking milk.

5.a.2 Methods

A selected population of acute stroke patients admitted to RLUH, all of whom had debatable swallowing problems, was included in this study. For instance patients with obvious swallowing problems or definite safe swallowing were not involved. In many cases, the safety of swallowing was questioned by speech and language therapists (SLT), who wanted more accurate information before taking management decisions. Therefore, these patients were characterised by the presence of equivocal signs in the swallowing assessment, and thus had a higher incidence of dysphagia than the whole study population. A standardised swallowing assessment (SSA), a videofluoroscopy (VFS) and a milk nasendoscopy (MNE) were performed within 48 hours of each other (80% within 24 hours). The investigators who carried out these procedures did not confer. The rate of chest infections and other information, as described in Chapter 3, were also recorded.

<u>Videofluoroscopy</u>

Patients were seated upright in a specially made VFS chair which can support patients with poor sitting balance and can also fit within the narrow gap of the fluoroscopic beam. They were given 3 teaspoonfuls of radiopaque liquid material (Gastromiro). After each spoonful a senior radiologist made a decision on safety, and in the absence

of obvious problems Gastomiro was given from a glass. However, if signs of aspiration were detected at any stage, 3 teaspoonfuls of barium thickened with carob bean flour (Carobel) were given.

Lateral and antero-posterior views of mouth and neck were recorded using a videocassette counter/timer recorder. At the end of the procedure, the radiologist reviewed the recording frame by frame for signs of penetration, aspiration, and transient or persistent pooling in the valleculae and pyriform fossae. **Penetration was defined as entrance of material up to, but not beyond, the vocal cords and aspiration as entrance of material beyond the vocal cords.** The occurrence of coughing during the procedure, together with its effectiveness in cleaning the airways, was also recorded. **Silent aspiration was defined as aspiration unaccompanied by cough or other obvious signs of distress.**

<u>Milk nasendoscopy</u>

Patients were seated upright, either at their bedside or in the otorhinolaryngology clinic. Prior to the investigation, the nasal cavity of the patients was treated with 0.5ml of 1% Cocaine solution. The distal end of a flexible fibreoptic nasendoscope was inserted, by an experienced otorhinolaryngologist, through the most patent nasal passage into the oropharynx at the level of the soft palate. This allowed a view of the base of the tongue, the epiglottis, valleculae, pyriform fossae and laryngeal inlet.

The swallowing of 3 teaspoons of milk was directly observed and in the absence of any aspiration a glass of milk was given. However, if signs of aspiration were detected at

any stage spoonfuls of milk thickened with Carobel were given. Signs of aspiration, penetration, coughing and pooling in the valleculae and pyriform fossae were recorded, as for the VFS procedure.

5.b RESULTS

5.b.1 General characteristics of the study population

Forty six patients, with a mean age of 70 years (standard deviation 1.9), were recruited to the study. Of these 62% were males and 49% had a right hemispheric stroke. Overall, 6 patients were excluded from the analysis because the instrumental investigations were not performed within 48 hours of each other. The reason for the delay was poor sitting balance in 3 patients who were not able to maintain the position required for VFS. This problem was later resolved by the use of the special VFS chair, though 1 bilateral amputee was unable to maintain sitting balance even in the VFS chair. Two further cases had to be excluded because of the unforseen absence of the study otorhinolaryngologist.

5.b.2 Detecting aspiration

Aspiration of either thin or thickened material occurred in 48% of patients in MNE and 73% in VFS, whereas unsafe swallowing was detected in 68% of patients assessed using the SSA. Patients without any evidence of aspiration or with signs of penetration only were included in the same category for this analysis.

Table 5.b.1 compares the findings of the SSA and MNE with those of VFS (treated as "gold standard"). The SSA was more sensitive though less specific than the MNE. Over 80% of the patients who aspirated during MNE or had unsafe swallowing in SSA also aspirated during VFS. On the other hand, over half of those who did not show signs of aspiration during MNE did aspirate during VFS.

These results indicate that neither MNE nor SSA can substitute the VFS in all cases. Nonetheless, VFS might be oversensitive in detecting aspiration which might be of little clinical importance. Thus, the predictive value in detecting chest infections was examined in each of these investigations.

5.b.3 Predicting chest infection

Patients who showed signs of aspiration during any of the three procedures, were at higher risk of developing chest infections compared to those with no aspiration or with signs of penetration only (Table 5.b.2).

Of the 13 patients who developed a chest infection, 12 (92%) aspirated in VFS or had unsafe swallowing in the SSA and 10 (77%) aspirated in MNE. Hence, both VFS and SSA are very sensitive in detecting patients at high risk of chest infections, but they are less specific. Over half of those who did not develop a chest infection aspirated in VFS or were found to have unsafe swallowing in the SSA. MNE, although less sensitive, proved to be more specific than the other two investigations.

Table 5.b.1 Comparison of Milk Nasendoscopy (MNE) and Standardised Swallowing Assessment (SSA) with Videofluoroscopy (VFS).

	VFS						
	Aspiration* n	No aspiration /Penetration only n	Sensitivity	Specificity	Positive Predictive value	Negative Predictive value	Likelihood Ratio
MNE:							
Aspiration *	16	3	55%	73%	84%	38%	2.02
No aspiration**	13	8					
SSA:							
Unsafe swallowing	22	5	76%	55%	81%	46%	1.67
Safe swallowing	7	6					

* Aspiration of either thin or thickened material beyond the vocal cords at any stage of the procedure
** Includes cases with penetration up to, but not beyond, the vocal cords

Table 5.b.2 Incidence of chest infection and the value of Videofluoroscopy (VFS), Milk Nasendoscopy (MNE) and Standardised Swallowing Assessment (SSA) in predicting chest infections.

	n	Chest infections n	Positive Predictive value	Negative Predictive value	Relative Risk (95% CI)
VFS:					
Aspiration*	29	12	41%	91%	4.6 (0.7-31)
No Aspiration**	11	1			
MNE:					
Aspiration *	19	10	53%	86%	3.7 (1.2-11.4)
No Aspiration**	21	3			
SSA:					
Unsafe swallowing	27	12	44%	92%	5.8 (0.8-40)
Safe swallowing	13	1			

* Aspiration of either thin or thickened material beyond the vocal cords at any stage of the procedure
** Includes cases with penetration up to, but not beyond, the vocal cords

Physicians for their clinical practice require the positive and negative predictive values ([+PV] and [-PV]) of a test, which indicate the probabilities of whether or not an event (ie chest infection) will occur. In this study, a large proportion of patients who were found at risk of aspiration in VFS and SSA, did not develop a chest infection (+PV<50%), although both investigations performed well in excluding the risk of developing chest infection in those patients who had "safe" swallowing (-PV> 90%). The relative risk of developing a chest infection was 5.8 in patients found to have unsafe swallowing by the SSA, compared to 4.6 in patients who aspirated in VFS, although the 95% confidence intervals were very wide because of small numbers.

By contrast the MNE, did not perform any better than the other two investigations. The +PV was higher though the -PV was lower than those of VFS and SSA, and the risk of developing a chest infection was 3.7-fold in patients who aspirated during the procedure.

5.b.4 Severity of dysphagia and risk of chest infection

The risk of developing a chest infection varies with the severity of dysphagia (Table 5.b.3). Patients who aspirated thickened material in the MNE had the highest risk of developing a chest infection, whereas patients with penetration only had a similar risk to those without signs of aspiration. The relative risks could not be calculated in patients who had a VFS, because of a division by zero. Likelihood ratios were used instead and showed a similar trend. The weak association of penetration with the incidence of chest infection was the reason for "penetration" being combined with "no

Table 5.b.3 Relative risks and likelihood ratio of developing chest infection during videofluoroscopy and milk nasendoscopy.

	Videofluoroscopy		**Milk nasendoscopy**	
	Relative Risk	Likelihood Ratio	Relative Risk	Likelihood Ratio
Aspiration of thickened fluids	NV*	2.08	4.4	8.31
Aspiration of fluids only	NV	1.34	2.36	1.56
Penetration only	NV	0.35	0.55	0.23
No Aspiration	---	NV	1	0.46

* Not Valid because of division by zero

aspiration" in this analysis.

5.b.5 Pooling in the pyriform fossae and risk of chest infection

The severity of pooling in the pyriform fossae was also shown to be a predictor of chest infections (Table 5.b.4). Persistent pooling conveyed the highest risk of developing chest infection, with a similar pattern in both VFS and MNE.

5.b.6 Coughing and risk of chest infection

Over 70% of patients in this study aspirated at least once and in many cases, aspiration was observed with more than one spoonful of barium or milk. Coughing may have occurred after some of these spoonfuls and not others. Of the 29 patients who aspirated during VFS, 9 (31%) were true silent aspirators with no clinical signs at any stage during the procedure, 13 (45%) coughed during some of the aspiration episodes but not others, while 7 (24%) always showed clinical signs. Of the 19 patients who aspirated during MNE, 3 (16%) were true silent aspirators, 7 (37%) were intermittently silent aspirators and 9 (47%) always showed clinical signs.

The rate of chest infection in patients who aspirated but always coughed effectively and cleared their airways, did not differ from those who had either episodes of silent aspiration or an ineffective cough which did not clear the airways (Fisher exact 2p= 1 for both VFS and MNE). This suggests that in patients at risk of aspiration but with good cough, this protective mechanism might fail occasionally during feeding.

Table 5.b.4 Absolute and relative risk (with 95% CI) of developing a chest infection in hospital, according to the degree of "pooling" in the pyriform fossae during videofluoroscopy and milk nasendoscopy.

	Pooling in Videofluoroscopy			Pooling in Milk Nasendoscopy		
	n*	n (%) chest infection	Relative risk (95% CI)	n	n (%) chest infection	Relative risk (95% CI)
Persistent	4	4 (100%)	6.3 (2.6-15.3)	10	7 (70%)	6 (1.5-23.3)
Transient	8	4 (50%)	3.1 (1.-9.7)	13	4 (31%)	2.6 (0.6-12.2)
None	25	4 (16%)	1	17	2 (12%)	1

* No information on "pooling" in 3 cases

5.b.7 Best combination of tests in predicting chest infection

Patients who aspirated in both VFS and MNE had the highest incidence of chest infections, but when aspiration in VFS was not accompanied by any significant abnormality in the SSA ("safe swallowing"), only 14% developed a chest infection (Table 5.b.5).

Only one episode of chest infection was recorded in patients without signs of aspiration in VFS, but this patient had aspirated in MNE and was found to have unsafe swallowing on the SSA (Table 5.b.6).

5.b.8 Adverse events

Videofluoroscopy and SSA were well tolerated by all patients. One patient suffered an episode of "collapse" 45 minutes after the MNE. This lasted a few minutes, but spontaneously recovered without treatment. The first opportunity to measure the vital signs was immediately after the recovery and these showed no abnormality.

Table 5.b.5 Inidence of chest infection according to results of milk nasendoscopy (MNE) and SSA in patients who aspirated during videofluoroscopy (VFS) .

	Aspirators in Videofluoroscopy	
	n	**Number of chest infections (%)**
ALL	29	12 (41%)
Aspiration in MNE	16	9 (56%)
No Aspiration in MNE	13	3 (23%)
Unsafe swallowing in SSA	22	11 (50%)
Safe swallowing in SSA	7	1 (14%)

Table 5.b.6 Incidence of chest infection according to results of MNE and SSA in patients who did not aspirate during VFS.

	Non Aspirators in Videofluoroscopy	
	n	**Number of chest infections (%)**
ALL	11	1 (9%)
Aspiration in MNE	3	1 (33%)
No Aspiration in MNE	8	0 (0%)
Unsafe swallowing in SSA	5	1 (20%)
Safe swallowing in SSA	6	0 (0%)

5.c DISCUSSION

5.c.1 Methodological issues

Clinical and instrumental assessments were carried out in a selected population of patients. All procedures were performed following a standard method (eg all patients were sat up at 90^0 during the assessments). VFS and MNE (but not SSA) involved administration of both normal and thickened fluids. The administration of thickened fluids does not improve the sensitivity of the procedure in detecting aspiration as stroke patients are more likely to aspirate thin fluids rather than thickened fluids or semisolids [85]. In this study, thickened fluids were given to aid speech and language therapists in taking management decisions, as well as obtaining a rough estimate of the severity of the swallowing problems. The texture of the contrast materials is quite different to the texture of water or milk, even when these are thickened with Carobel, however. The oily texture of Gastromiro and the very smooth paste of barium may have facilitated aspiration.

Both the radiologist and the otorhinolaryngologist were experienced with the instrumental investigations, although nasendoscopy had not previously been used in that hospital for the detection of aspiration. Thus, the sensitivity of MNE might improve with the increasing experience of the operator.

Cocaine solution sprayed in the nasal cavity a few minutes before the MNE is used to anaesthetize the mucosa and make the procedure more tolerable. Although in this study a quarter of the usual dosage was administrated, the possibility that swallowing was

affected during and for a few hours after the procedure cannot be excluded. Therefore, the sequence of the assessments is important to account for these effects.

The SSA was always carried out before the first instrumental procedure, then 21 VFSs were performed before the MNE, 7 within 4 hours after MNE, and the remaining 12 more than 12 hours after MNE. This sequence was dependent on the availability of the investigators and instruments, and therefore it was not randomly allocated. Of those 7 patients who had a VFS within 4 hours after MNE, 4 aspirated and 3 did not aspirate during VFS. Of those 4 who aspirated during VFS, 3 did not aspirate in MNE. By contrast, 2 out of 3 patients who did not aspirate during VFS also did not aspirate during MNE.

In a large proportion of patients, swallowing improvement is expected during the first two weeks of stroke [66]. Swallowing might have improved during the period of 24 to 48 hours between the two instrumental investigations. Although this may be true early after an acute stroke, in this study patients were examined at least one week after stroke onset, when changes are likely to occur more gradually. Furthermore, over half of the procedures were carried out on the same day.

Aspiration was not observed during all swallows in patients with mild dysphagia. It is therefore possible that differences in the detection of aspiration between procedures may be due to those patients who aspirated intermittently. For example, if aspiration occurs in one out of ten swallows, it is likely that this will occur in only one of the two instrumental investigations.

Patients with signs of penetration of material up to, but not beyond, the laryngeal opening were regarded as "normal" from the point of view of aspiration. Our own data and the literature [42, 56, 144] both indicate that penetration is a sign of dysfunction and not a serious abnormality.

The diagnosis of chest infection was made independently by the patient's medical team. Obviously, with large numbers of acute stroke patients scattered in many medical wards, under the care of different medical firms, it was not possible to base the diagnosis of chest infections on investigations such as chest-X-rays, sputum cultures etc. It is unlikely that clinicians, who were not involved with the study, will be biased by the presence of swallowing problems, but they might tend to overdiagnose chest infections in patients with more severe strokes. This would make the proportion of chest infection higher in patients with dysphagia, as these are associated with more severe strokes.

The medical notes were checked for evidence of chest infections by the author at the day 3 assessment and around the time of discharge from hospital. Although the author was not aware whether or not a diagnosis of chest infection had been made at the time of the swallowing assessments, it might nevertheless have been obvious from the clinical state of the patient. Thus, swallowing problems might have been diagnosed more often in patients with chest infections.

5.c.2 Discussion of the results

The sensitivity and specificity of the SSA in detecting patients at risk of aspiration compared with VFS were very similar to those found in Smithhard's study [143], which was carried out on consecutive stroke patients using the SSA (see Table 2.c.3). Differences in the predictive values can be explained by the differences in the prevalence of the observed abnormalities (ie aspiration during VFS).

In Kidd's study [93] clinically detected dysphagia was defined as inability to drink 50mls water given in ten 5ml aliquots. This clinical swallowing assessment performed well in detecting risk of aspiration compared with VFS (Table 2.c.3). However, in the present study, inability to complete 60mls water was more sensitive (79% versus 76%) though less specific (45% versus 55%) in detecting risk of aspiration in VFS than the overall SSA.

The value of the SSA in predicting chest infections is examined in Chapter 7 (dysphagia and outcome).

The MNE did not perform any better than the SSA either by comparison with VFS or in predicting chest infections. Therefore, the value of MNE should be considered together with other advantages or disadvantages of the techniques.

Patients, who coughed effectively and cleared their airways whilst they were aspirating, did not appear to be protected from chest infections. Oral feeding restrictions may be a confounding factor, if they appeared more often in one group than the other.

5.c.3 Advantages and disadvantages of the SSA, VFS, and MNE

The SSA is simple, safe, and can be carried out in a few minutes by the patient's bedside. It can be used soon after the stroke and frequently repeated, even in patients with poor sitting balance, or with communication problems. As only fluids are given, the main use of the SSA is for screening patients for dysphagia, identifying those who are at risk of aspiration. Feeding precautions can be taken immediately, while awaiting a speech and language therapist's assessment.

The VFS is also a safe procedure. The radiological equipment is now widely available, although a specially made chair is required for patients without sitting balance. It takes 20-30 minutes of a radiologist's and a radiographer's time. The help of auxiliary staff is also required for bed to chair transfers. The videorecording allows a detailed examination of each swallow and the technique appears to be very sensitive in detecting pooling of fluids within the pyriform fossae, penetration or aspiration. (Although, it is questioned whether small amounts of aspiration detected in VFS matter [143]).

At the time of this study, stroke patients had a restricted access to VFS in the Liverpool hospitals. The investigations performed for this study had been obtained for research purposes at a cost of £75/each.

The MNE can be carried out by the bedside, if necessary, and requires 20 minutes of the time of an otorhinolaryngologist and a helper to administer the milk. Although the technique has been described as safe, the adverse event experienced by one patient may be attributed to bradycardia caused by central vagal stimulation. This is a recognised

effect of small doses of cocaine which can be absorbed through the mucosa [27].

MNE does not provide the detailed anatomical information of the VFS, although can detect pooling of material in the pyriform fossae. Aspiration may occur quickly, so that videorecording may provide additional information. Transporting this equipment to the patient's bedside is inconvenient, however. The cost appears to be less than the cost of VFS, though the MNE investigations were not costed for this study.

The passage of the nasendoscope through the nasal cavity is unpleasant, though attenuated by the local anaesthetic and none of the patients complained. A formal study of the patients preferences has not been carried out, however.

Chapter 6

NATURAL HISTORY OF DYSPHAGIA IN ACUTE STROKE

6.a AIMS AND METHODS

6.a.1 Aims

The incidence and course of dysphagia during the first four weeks after stroke onset are examined in this chapter. Knowledge of the incidence of dysphagia in different subgroups is useful for screening and management purposes. Although improvement of swallowing problems is expected in stroke survivors, the speed and extent of these changes still needed to be studied. Knowledge of the factors which might predict improvement of swallowing would be a great help in the clinical management of dysphagia. The search for such predictive factors is described in the last section of this chapter.

6.a.2 Methods

Initially, the general characteristics of patients, who were consecutively admitted to each of the two Liverpool teaching hospitals with an acute stroke, were compared to find out whether differences in the incidence of dysphagia could be explained by different characteristics of the study population. The incidence of swallowing problems detected by the SSA was then related to various "risk factors", and the subgroups with increased risk of dysphagia were identified. The clinical course of dysphagia was followed up by

repeated swallowing assessments. Factors that appeared to predict improvement were examined, and discriminant function analysis was used to try to identify the most useful predictors of recovery.

6.a.3 Clinical Assessments

The clinical assessments have already been described in Chapter 3. For the present analysis items from the neurological assessment were combined to form composite measures of "speech/communication", "inattention/gaze paresis" and "weakness of arm or leg", using the following criteria:

<u>Speech/Communication</u>

Patients fully orientated and not dysphasic were considered "normal"; otherwise "impaired or limited".

<u>Inattention/Gaze paresis</u>

Patients with no gaze paresis and with no visual inattention or hemianopia were "normal"; otherwise "impaired".

<u>Weakness of Arm or Leg</u>

"None": no weakness of arm and leg.

"Mild": weak arm or leg but able to move against resistance (MRC grade 4).

"Severe": greater impairment than in the "mild" group (MRC grade <4)

6.a.4 Statistical analysis

Univariate analysis was used to produce contingency tables so that differences between subgroups or hospitals could be identified. The statistical significance of these differences was tested with Chi-square statistics.

Variables predicting swallowing recovery identified in univariate analysis were then combined into a linear discriminative function to increase the overall predictive power. To do this, the whole dataset was split into two roughly equal parts (Data-subsets A and B). The split was "pseudo-random" (ie haphazard) as the software for random splitting of the data was not available at that time.

The discriminant function was derived on "subset A" only, using Wilks' lambda as the test of significance. The predictive accuracy "goodness of fit" of this function was then tested on "subset B", using classification analysis. This technique computes the proportion of correctly predicted cases in each group.

6.b GENERAL CHARACTERISTICS OF THE STUDY POPULATION

A stroke register was kept in each hospital for the duration of the study. Overall 1229 acute stroke patients were registered at the two hospitals during the study period. The average admission rate was marginally higher at BGH (29 patients/month) than at RLUH (25 patients/month).

A third of the registered patients were excluded from the dysphagia study (Table 6.b.1). The initial diagnosis of stroke was not confirmed in 4% of the cases recorded in the stroke register. The main alternative diagnosis were transient ischaemic attack (TIA), deterioration in neurological signs due to a previous stroke (usually due to intercurrent illness), brain tumour and post epileptic syndrome (Todd's paresis). Patients who died within 24 hours (8% of all cases), or who were not identified within 48 hours (5%), were also excluded. During holiday periods and absence of the investigators, study recruitment was interrupted, resulting in the exclusion of 16% of the patients. The proportion of patients excluded was not significantly different ($p = 0.42$) between the two hospitals.

Of the remaining 757 patients, who were included in the study, 516 (68%) were registered at RLUH and 241 (32%) at BGH. Patients admitted 48 hours or more from onset of stroke (8% at RLUH and 10% at BGH) were not seen for the "day 1" assessment, but subsequent assessments were carried out.

Table 6.b.2 shows the general characteristics of the study population in each hospital. The mean age of all patients was 72.3 (SD 11.6) and 54% were female. A small proportion (6%) had previously been severely disabled and a similar proportion (6%) had suffered two or more strokes in the past, whereas 72% of the patients were admitted with their first ever stroke. BGH admitted significantly ($p < 0.01$) more patients with a previous disability or handicap.

Overall 49% of patients had a stroke affecting the right side of the body and small proportions were admitted with no laterising signs (7%) or had bilateral signs (2%).

Table 6.b.1 Number of patients included /excluded from the study.

	RLUH n (%)	**BGH n (%)**	**Combined hospitals n (%)**
Recruitment period	30 months	13 months	
Patients in the Stroke Register	746 (100%)	383 (100%)	1129
Patients excluded from the study:			
"not a stroke after all"	30 (4%)	20 (5%)	50 (4%)
dying within first 24 hours of admission	48 (6%)	39 (10%)	87 (8%)
not identified within 48 hours of stroke onset	37 (5%)	23 (6%)	60 (5%)
interrupted recruitment period	115 (15%)	60 (16%)	175 (16%)
Total number of patients included in the study	516 (69%)	241 (63%)	757 (67%)

Table 6.b.2 General characteristics of the study population.

	RLUH	BGH	p*
All:	516	241	
Age: ≤64	24%	20%	
65-74	31%	30%	p= 0.32
≥75	45%	50%	
mean [SD]	71.7 [12]	73.4 [10.4]	p= 0.08
Sex: Female	52%	57%	p= 0.19
Previous disability◆:			
None	66%	51%	p< 0.01
Mild	29%	41%	
Severe	5%	8%	
Previous stroke	28%	29%	p= 0.84
Side of body affected:			
Right side	49%	49%	
Left side	41%	42%	p= 0.20
Both	(2%)	(4%)	
Neither	8%	5%	
Conscious level (on admission):			
Alert	73%	77%	
Drowsy	17%	12%	p= 0.16
Stupor/Coma	10%	11%	
Stroke severity◆ (on admission):			
Very severe	29%	40%	
Severe	20%	22%	p< 0.01
Moderate	25%	17%	
Mild	27%	21%	
OCSP Classification◆◆:			
TACS	17%	18%	
PACS	33%	27%	
LACS	14%	5%	p< 0.01
POCS	6%	8%	
Unclassifiable	30%	42%	
Discharge destination:			
Home	56%	52%	
Institution	16%	13%	p= 0.38
Other hospital or rehabilitation unit	1%	1%	
Dead	27%	33%	
Length of stay:			
Median	22 days	15 days	p< 0.01
1st Quartile	10	8	

* Refers to the association between the proportions in each subgroup and hospitals

◆ For the criteria used to group patients refer to Chapter 6.a.1

◆◆ For the criteria used to group patients refer to Chapter 3.c.2

(Percentages based on ≤10 cases are in brackets)

Conscious level on admission was decreased (drowsy) in 15% of the cases and a further 11% were in a stupor or coma.

Marked differences were observed in stroke severity, measured by the Scandinavian Stroke Scale (SSS), as significantly more patients with severe or very severe stroke were admitted at BGH than at RLUH. This was not explained by differences in the conscious level or in the proportion of TACS (the "most severe" OCSP subgroup). There were differences in the proportion of cases that could not be classified by the OCSP system (30% of the cases at RLUH and 42% at BGH), however. Most of the unclassified cases were due to non-assessable neurological signs, especially visual fields: 10% at RLUH versus 17% at BGH. Furthermore, 7% at RLUH and 11% at BGH had residual neurological signs from a previous stroke.

Most of the differences in the length of stay between the two hospitals were within the group of patients who were discharged to institutional care (mean 61 days at RLUH versus 53 days at BGH) and those who died in hospital (23 days at RLHU versus 14 days at BGH).

6.c INCIDENCE OF DYSPHAGIA

Of all patients assessed by SSA on day 1, swallowing was judged "safe" in 54%, "possibly unsafe" in 12% and "definitely unsafe" in 18%. The remaining 17% could not be assessed because they were unconscious, had no head control, or were otherwise

too ill to be considered for oral feeding. The incidence of dysphagia did not significantly differ ($p = 0.8$) between hospitals (Table 6.c.1).

Tables 6.c.2 and 6.c.3 show the proportion of assessable patients with unsafe swallowing (possible or definite) on day 1, in different subgroups. Older patients or patients with previous disability or immobility, were more likely to have swallowing problems ($p < 0.01$). There was no statistically significant difference in the incidence of dysphagia between men or women, those with left or right sided signs and those with or without a previous stroke.

Over two thirds of patients who were either drowsy, had a very severe stroke or were admitted with TACS, were found to have unsafe swallowing on day 1. The incidence of dysphagia was lower in patients with a mild stroke or with a lacunar syndrome (LACS).

6.d NATURAL COURSE AND RESOLUTION

Fig 6.d.1 shows the proportion of patients whose swallowing improved or deteriorated after the assessment on day 1. Of those with unsafe swallowing on day 1, 21% improved (ie became safe) by day 3, and 47% by day 28. If we assume that swallowing had recovered in patients discharged alive before being assessed, then over half of the initially dysphagic patients appeared to have regained safe swallowing by the end of follow-up. Cases with missing information (9 on day 3 and 8 on day 7) were considered as "non-improvers".

Table 6.c.1. Incidence of dysphagia on day 1.

	RLUH n (%)	BGH n (%)	Combined hospitals n (%)
ALL	474	202	676
Safe swallowing	260 (55%)	104 (52%)	364 (54%)
Possibly unsafe swallowing	54 (11%)	27 (13%)	81 (12%)
Definitely unsafe swallowing	83 (18%)	36 (18%)	119 (18%)
Swallowing not assessable	77 (16%)	35 (17%)	112 (17%)

Table 6.c.2. Proportion of patients with unsafe swallowing on day 1 in different subgroups.
(Patients not "assessable" on day 1 by SSA are excluded)

	RLUH		BGH		Combined hospitals	
Subgroups	**n**	**% unsafe swallowing**	**n**	**% unsafe swallowing**	**% unsafe swallowing**	**p***
ALL	397	35%	167	38%	35%	p= 0.8
Age:						
≤64	100	23%	35	26%	24%	
65-74	124	38%	57	42%	39%	p< 0.01
≥75	161	39%	75	40%	39%	
Sex:						
Female	197	36%	88	41%	38%	p= 0.25
Male	189	32%	79	34%	33%	
Side of body affected:						
Right	188	35%	88	43%	37%	
Left	161	35%	64	34%	35%	p= 0.63
Both	1	(100%)	3	(0%)	25%	
None	32	28%	11	27%	28%	
Previous stroke :						
None	240	34%	121	37%	35%	p= 0.51
One or more	77	39%	45	38%	39%	
Previous disability:						
None	267	30%	88	35%	31%	
Mild	100	39%	63	37%	38%	p< 0.01
Severe	15	73%	11	46%	62%	
Previous mobility:						
Fully mobile	253	27%	100	37%	30%	
Mobile indoors	113	43%	56	32%	39%	p< 0.01
Immobile	16	75%	8	(63%)	71%	

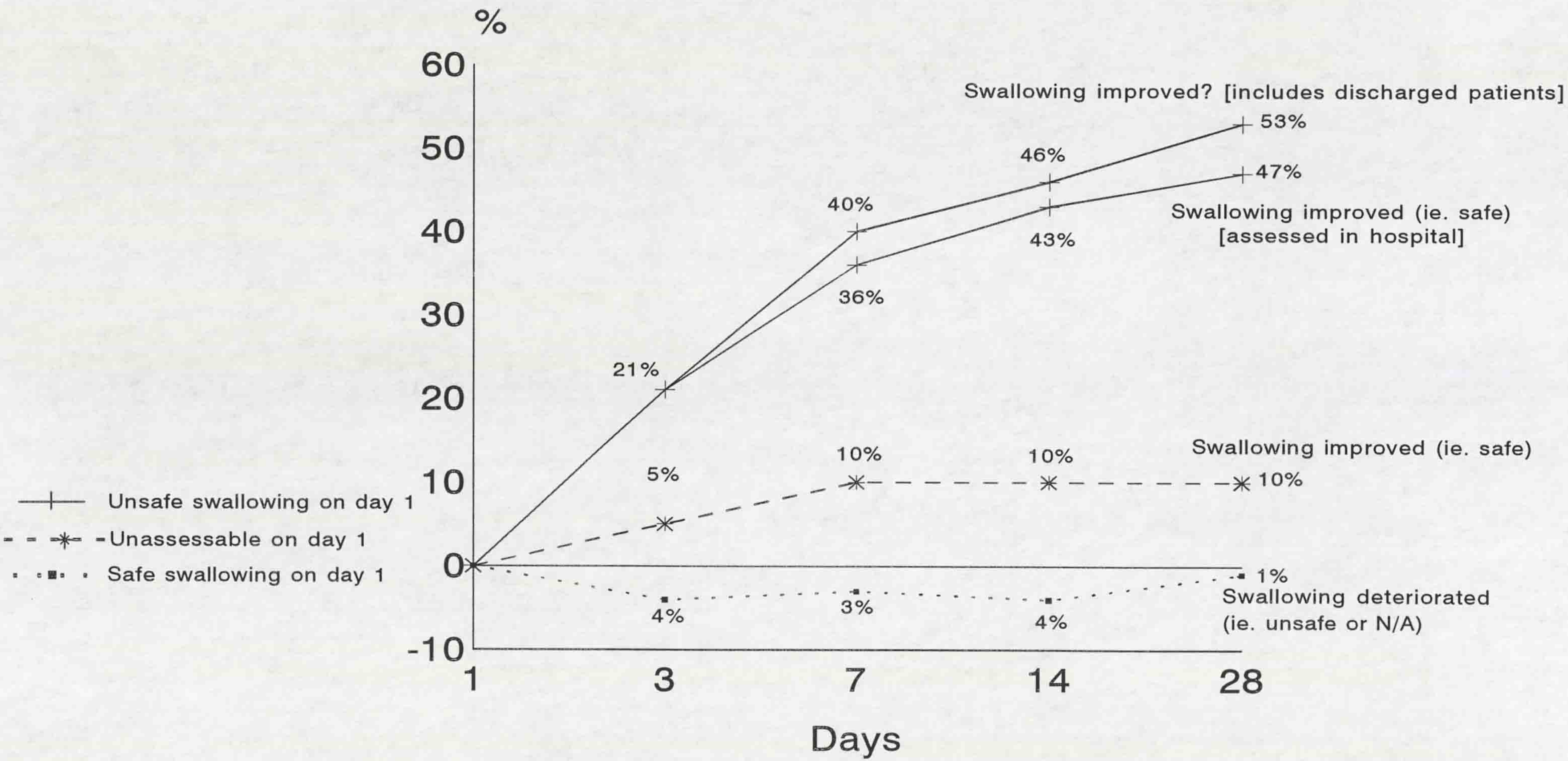
* Refers to the association between unsafe swallowing and each "risk factor" for both hospital combined.
(Percentages based on ≤10 cases are in brackets)

Table 6.c.3. (cont. from Table 6.c.2) Proportion of patients with unsafe swallowing on day 1 in different subgroups.
(Patients not "assessable" on day 1 by SSA are excluded)

	RLUH		BGH		Combined hospitals	
Subgroups	**Total No**	**% unsafe swallowing**	**Total No**	**% unsafe swallowing**	**% unsafe swallowing**	**p***
Conscious level:						
Alert	350	30%	128	28%	29%	p<0.01
Drowsy	42	69%	35	71%	70%	
Stroke severity:						
Very severe	68	74%	47	72%	73%	
Severe	86	43%	43	44%	43%	p<0.01
Moderate	117	27%	35	17%	25%	
Mild	124	14%	42	10%	13%	
OCSP Classification:						
TACS	78	69%	41	66%	68%	
PACS	165	27%	65	28%	27%	
LACS	69	10%	13	15%	11%	p<0.01
POCS	29	24%	18	39%	30%	
Unclassifiable	56	45%	30	30%	41%	

* Refers to the association between unsafe swallowing and each "risk factor" for both hospital combined.

Fig 6.d.1 Proportion of patients who improved or deteriorated since swallowing assessment on Day 1



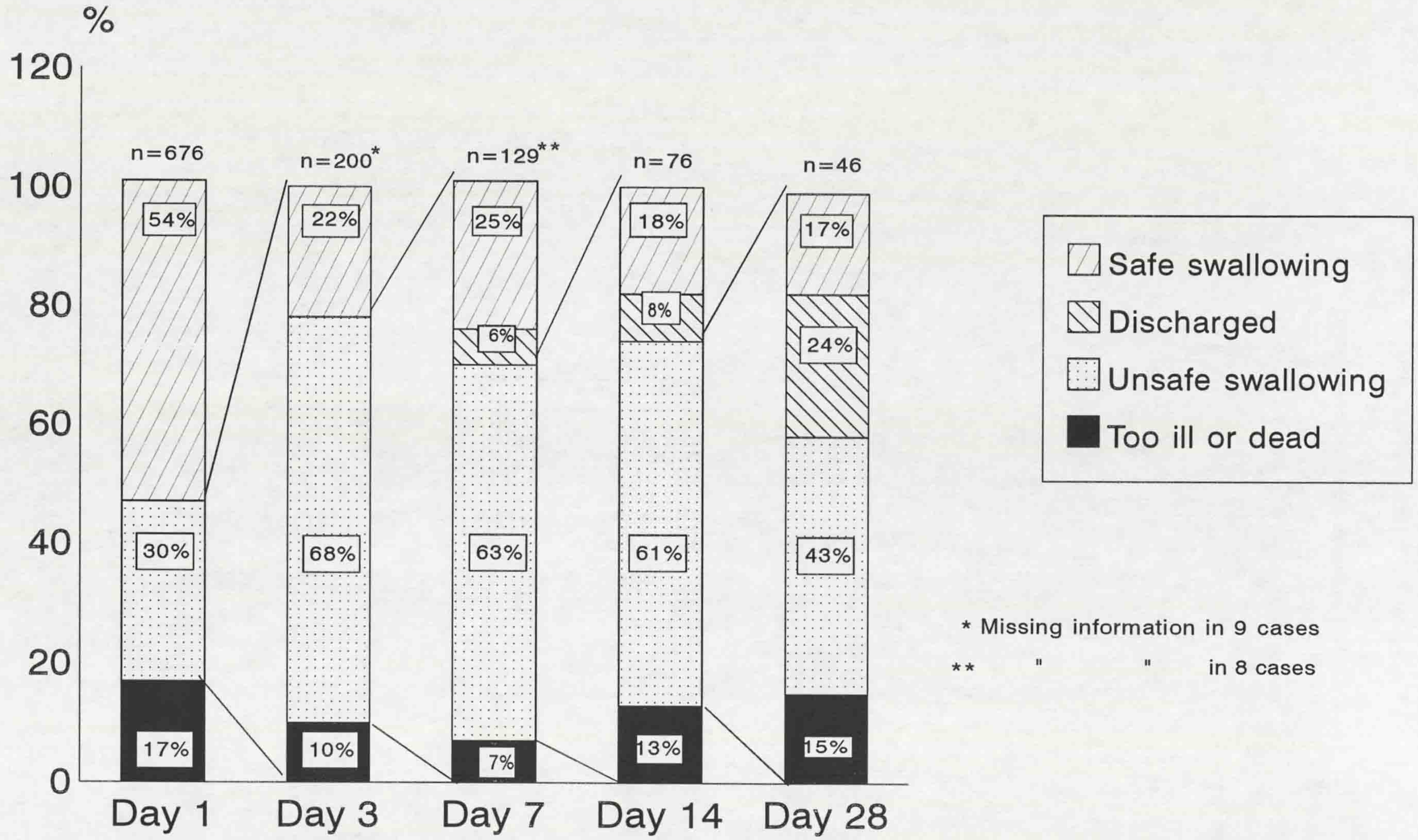
Of those who were not well enough to have their swallowing assessed on day 1, 5% recovered safe swallowing by day 3 and a further 5% by day 7. Of those with safe swallowing on admission, 4% deteriorated (ie unsafe swallowing or not assessable) by day 3, but most of these had recovered by day 28.

Fig 6.d.2 shows the course of dysphagia (ie improved / deteriorated / unchanged) between assessments in patients who had unsafe swallowing at the previous assessment. For instance, of the patients who had swallowing difficulties on day 1, about two thirds were still unsafe on day 3, and the remaining one third either achieved safe swallowing or were too ill to be assessed or had died. A similar pattern was observed between the day 3 and day 7 assessments in patients who had unsafe swallowing on day 3, and between the day 7 and day 14 assessments in patients who had unsafe swallowing on day 7. At the last swallowing assessment on day 28, less than half of the patients who had unsafe swallowing at the previous assessment were still in hospital with dysphagia, though some of the patients who had been discharged from hospital by that stage, could still have had swallowing problems.

6.e PREDICTORS OF LIKELIHOOD OF RECOVERY

In the two hospitals combined, 200 patients were found by the SSA to have some degree of swallowing difficulty on day 1. By day 3, 42 of these patients had recovered normal swallowing, though information was missing in 9 cases. Patients who died during the first 3 days were considered as "non-improvers" in this analysis.

Fig. 6.d.2 The course of dysphagia between swallowing assessments



* Missing information in 9 cases

** " " in 8 cases

The data file was divided in two parts (subsets A & B). Tables 6.e.1 and 6.e.2 show the percentage of patients with improved swallowing in different subgroups in the two subsets, together with the Chi-square significance levels for the combined dataset (where valid). Because of small numbers, conventional "p-values" could not be used as the only criterion for selecting predictive variables. (Some Chi-squared values were not valid because of low expected cell frequencies). Therefore, the selection was based on the differences in the proportion of "improvers" in each subgroup, provided these were reasonable, and consistent in both subsets. Variables with non-ordered categories (eg OCSP classification subtypes) were excluded and inter-dependent variables were avoided.

Variables such as facial movements, speech/communication and visual fields/gaze paresis fulfilled the conditions for entry into the discriminant function analysis (DFA), as those with no impairment were more likely to improve their swallowing by day 3. Overall "stroke severity" was measured by the Scandinavian Stroke Scale (SSS) score, which includes several of the above variables, so that the total score was not used in the DFA. Other variables that might have been predictors of swallowing improvement, such as voluntary cough and gag reflex, were excluded from the DFA as they could not always be assessed (missing values). Finally, the number of previous strokes appeared to be a good predictor, and was therefore used in the analysis.

The four variables included in the analysis and the discriminant function derived from the "subset A" are shown in Table 6.e.3. The relative magnitudes of the standardised discriminant function coefficients indicate which variables contribute most to the group

Table 6.e.1 Proportion of patients with swallowing improved by day 3 of those with unsafe swallowing on day 1, in different subgroups.

	Subset A		Subset B		Combined Dataset
Subgroups	**n**	**% swallowing improved by day 3**	**n**	**% swallowing improved by day 3**	**p***
Patients with unsafe swallowing on day1**	75	27%	116	19%	
Age: ≤64	13	23%	19	21%	
65-74	26	31%	43	19%	0.96
≥75	36	25%	49	18%	
Sex: Female	42	29%	61	20%	0.64
Male	33	24%	50	18%	
Previous disability:					
None	39	31%	65	22%	
Mild	26	31%	35	20%	NV
Severe	7	(0%)	8	(0%)	
Previous stroke:					
None	41	34%	80	23%	<0.05
One or more	19	16%	26	4%	
Side of body affected:					
Right side	42	17%	60	22%	
Left side	29	41%	42	19%	0.36
Both	0	-----	1	(0%)	
Neither	3	(33%)	8	(0%)	
Conscious level (on admission):					
Alert	50	26%	76	20%	0.8
Drowsy	20	30%	30	20%	
Stroke severity (on admission):					
Very severe	33	18%	48	13%	
Moderate /Severe	32	28%	56	21%	NV
Mild	9	(56%)	12	33%	
OCSP Classification:					
TACS	35	20%	41	15%	
PACS	20	40%	39	21%	
LACS	5	(60%)	4	(50%)	<0.01
POCS	2	(50%)	11	46%	
Unclassifiable	13	8%	21	5%	

* Refers to frequency table for improved swallowing /unchanged swallowing by different predictive factors
** Patients who deceased by day 3 had been coded as "swallowing not improved"
NV= Chi-squared not valid because of low expected cell frequencies

(Percentages based on ≤10 cases are in brackets)

Table 6.e.2 (cont. from Table 6.e.1) Proportion of patients with swallowing improved by day 3 of those with unsafe swallowing on day 1, in different subgroups.

		Subset A		Subset B	Combined Dataset
Subgroups	**n**	**% swallowing improved by day 3**	**n**	**% swallowing improved by day 3**	**p**
Speech/Communication◆:					
Normal	19	32%	42	29%	0.08
Impaired or limited	56	25%	74	14%	
Visual field◆:					
Normal	20	40%	33	24%	0.09
Impaired	55	22%	83	17%	
Facial movements:					
Normal	11	64%	28	25%	<0.05
Impaired	61	21%	86	17%	
Weakness of affected limbs◆:					
None	6	(50%)	21	19%	
Mild	8	(38%)	13	31%	0=47
Severe	59	25%	82	18%	
Voluntary cough:					
Normal	20	40%	43	28%	0.05
Weak or absent	29	17%	36	17%	
Gag reflex:					
Normal	24	38%	28	29%	0.17
Reduced or absent	49	22%	88	16%	

◆ For the criteria used to group patients refer to Chapter 6.a.1

(Percentages based on ≤10 cases are in brackets)

Table 6.e.3 Discriminant function (DF) analysis and classification analysis on "**Subset A**"

Variables in analysis	**Standardised discriminant function coefficients**
Facial movements	0.77
Number previous strokes	0.63
Visual fields/Gaze paresis	0.28
Speech/Communication	0.22

Canonical discriminant functions			
Eigenvalue	**Canonical correlation coefficient**	**Wilks' lambda**	**p**
0.21	0.416	0.827	0.05

Classification analysis on "Subset A" using the DF equation derived from the same dataset		
	n	**n (%) correctly classified by**
Unsafe swallowing day 1, unchanged by day 3	36	32 (89%)
Unsafe swallowing day 1, safe by day 3	17	6 (35%)

Table 6.e.4 Classification analysis on "**Subset B**"

Classification analysis on "Subset B" using the DF equation derived from "Subset A"		
	n	**n (%) correctly classified**
Unsafe swallowing day 1, unchanged by day 3	81	57 (70%)
Unsafe swallowing day 1, safe by day 3	19	8 (42%)

differences. The square of the canonical correlation coefficient estimates the proportion of the variability in the discriminant function scores which is accounted for by being a "case" (ie showing improvement in swallowing) or a "non-case" (ie a non-improver). By contrast, the Wilks' lambda estimates the proportion of the total variability not explained by group differences.

Overall, the combined variables had only a modest ability to discriminate between those whose swallowing improved and those who did not (only 17% of the variability in the discriminant function scores were attributed to "between group differences"). However, 22 cases were not processed in the analysis because of missing values. Using classification analysis on the same "subset A" from which the discriminant function was derived, the sensitivity of the model for identifying improvers was 35% and specificity 89%. Overall, 72% of the cases were correctly classified.

Table 6.e.4 shows the results when the same formula was applied to the test "subset B". The overall percentage of correctly classified cases was lower (65%), though the sensitivity for "predicting" those whose swallowing improved was 42%. Overall, 19 out of 100 patients in "subset B" showed improvement in swallowing, so the "pre-test probability" was 19%, compared to a "post-test probability" of 25% in those in whom the model predicted improvement.

It was possible that not all of the four combined variables were contributing to the DF and the numbers in each subset were small, so there is wide uncertainty in the estimates. Therefore a step-wise DFA was carried out on the whole data file. This

"solution" may explain better group differences and select a smaller number of variables. The computed equation first considers the variable which best discriminates between the groups, then the next variable is added, which most improves the discriminant ability of the equation, and so on, until either all variables are entered into the equation or adding further variables does not improve discriminant power.

It is expected that this discriminant function would yield the best fit on the data file from which it was derived. Two of the four variables were dropped from the model and the two variables that remained ("facial movements" and "number of previous strokes") were only able to correctly classify improvers or non-improvers in 71% of cases (sensitivity 36%).

The DFA analysis was also repeated for those who improved to safe swallowing (n= 72) within the first 7 days. The discriminant function, however, was of no value, as Wilks' lamba did not achieve statistical significance.

6.f DISCUSSION

6.f.1 Methodological issues

The incidence and course of dysphagia were examined in an unselected population of acute stroke patients consecutively admitted to hospital.

The diagnosis of stroke was based on clinical signs, however brain imaging scans were

performed in about one third of the patients. Subarachnoid haemorrhage has a different clinical course and patients are normally referred to neurosurgical departments, and thus were not included in this study.

Diagnosis of recurrent stroke in patients while in hospital was not attempted because of practical difficulties in distinguishing recurrent from progressing stroke. Some degree of neurological deterioration is expected in up to 40% of patients admitted to hospital early after a stroke [29, 45, 72]. In this study, the first assessment was usually nearly 24 hours after stroke onset. Nonetheless, 19% of all patients showed a drop in Scandinavian Stroke Scale score between day 1 and day 3 assessments.

During the absence of the investigator, follow up assessments were carried out by a colleague. This accounted for a very small proportion of the assessments, so in this context interobserver reliability was not a major issue.

On the other hand, the neurological and swallowing assessments were performed by different observers at RLUH and BGH. Some of the Table 6.b.2 differences in "case mix" (OCSP classification) between the two hospitals are due to differences in the proportion of signs rated "unassessable" by these two observers. This has also been suggested by wider studies which showed that different "thresholds of uncertainty" in rating key neurological signs are an important source of variation [14, 15].

6.f.2 Discussion of the results

The study of the incidence and course of dysphagia provides valuable information for

the management of dysphagia and organisation of services. Among patients admitted to hospital early after a stroke and well enough to be considered for oral feeding, 35% are found to have some degree of swallowing impairment when assessed by the SSA. This proportion is very close to that obtained from the combined findings of previous studies on clinically detected dysphagia in acute stroke (see Table 2.d.1).

The incidence of dysphagia did not differ significantly between the two Liverpool teaching hospitals, suggesting that the findings of this study using SSA to detect dysphagia can be generalised to other large general hospitals treating relatively unselected patients. In Smithhard's study [143], however, half of the 112 patients assessed using the SSA, within 24 hours of stroke onset, were found to have unsafe swallowing. Manchester patients may have been assessed earlier, as many were examined in the Accident and Emergency department. Differences in preselection of cases "considered for oral feeding" could be another explanation.

The results from both hospitals confirm that although dysphagia is more frequent in patients with severe strokes, a significant proportion of those with milder strokes can still have swallowing problems. Thus, for detecting dysphagia and taking adequate feeding precautions all patients should have a swallowing assessment soon after stroke.

Most of the feeding restrictions are likely to be temporary, as about half of the patients with dysphagia improve to safe swallowing during the first fortnight. The mortality amongst the remainder is high, so that only 10% of those who had dysphagia on admission are still in hospital with swallowing problems a month after the stroke.

Patients with safe swallowing on admission should still be observed for signs of neurological and swallowing deterioration. In the small proportion of patients (4%) whose swallowing deteriorated after admission to hospital, overall neurological deterioration was also observed in every case.

Tube feeding is usually considered for patients with persisting swallowing problems. Attempts at nasogastric feeding are often unsatisfactory. Percutaneous gastrostomy feeding generally provides better nutritional support, though there is clinical uncertainty about the optimum time for tube insertion [86]. The ability to predict which patients are likely to have more persistent dysphagia would improve management. Unfortunately, I was unable to identify consistently predictors of improvement in this study.

The management of dysphagia demands careful attention to safe feeding to avoid complications. The association of dysphagia with complications and outcome will be examined in the next chapter.

Chapter 7

DYSPHAGIA AND OUTCOME

7.a AIMS AND METHODS

7.a.1 Aims

In this chapter, the effects of dysphagia on outcome are estimated. Poor prognostic factors (ie severe stroke, pre-stroke disability, older age, conscious level on admission) are associated with adverse outcome, and as shown in the last chapter, dysphagia is strongly related to some of these. It is therefore important to allow for these confounding factors when assessing the independent effect of dysphagia on outcome.

7.a.2 Outcome indicators

The incidence of chest infection, length of stay in hospital, discharge destination and fatality rates were compared in patients with or without swallowing problems soon after the onset of stroke. Differences in outcome were examined initially for the whole group of patients and then within various prognostic subgroups.

The effects of dysphagia on functional outcome, measured by the Barthel Index (BI) at discharge from hospital, were then examined within each prognostic subgroup. Finally, those factors most strongly associated with functional outcome were entered in a multiple regression analysis, together with dysphagia, to control for their intercorrelations and to estimate the independent association of swallowing problems with poor outcome.

7.a.3 Statistical analysis

Use of parametric methods to compare group means requires interval level measurements and homogeneous group variance. The length of stay (LOS) is an interval measure but its distribution is heavily skewed to the right and Bartlett's test showed no homogeneity of variance. Logarithmic transformation of the LOS made the subgroup variances more homogeneous and thus allowed comparisons using parametric significance tests (eg one-way ANOVA). Where this was not possible, non-parametric tests (eg Kruskal-Wallis) were carried out.

Although the Barthel Index is not strictly an interval scale, it may be treated as one for some purposes, so the arithmetic means of the total BI scores were also calculated. The distribution cannot be "normalised" by transformation, therefore only non-parametric significance tests (eg Kruskal-Wallis) were used. An alternative (though less sensitive) approach, which makes no assumptions about the level of measurement, is to split the distribution of Barthel scores into roughly equal groups (tertiles) and to examine the influence of dysphagia within subgroups using chi-squared tests.

Finally, step wise multiple linear regression analysis, using the total BI score at discharge as the dependent variable, was carried out to estimate the proportion of the variance of the total BI score which can be explained by each prognostic factor. The analysis was performed for survivors only and then repeated, giving a discharge Barthel score of -10 to those who died in hospital.

7.b INCIDENCE OF CHEST INFECTION

A diagnosis of possible or definite chest infection (see Chapter 3.d) was made at some stage during hospital stay in 20% of the patients who had been assessed with SSA on day 1. Patients with dysphagia had a 4-fold higher risk of developing a chest infection regardless of whether they had been rated as "possibly unsafe" or "definitely unsafe" (Table 7.b.1).

Overall, 71% of the chest infections ("possible" and "definite") occurred during the first week after stroke onset, but the proportion was 75% in those with unsafe swallowing on day 1, whereas only 61% of the chest infections, which did occur in those with safe swallowing, happened in the first 7 days. The relative risk for developing a chest infection during the first week was 4.9 (95% Confidence Intervals 3.0 - 8.0, $p < 0.01$) in those with dysphagia. The cumulative incidence of the first chest infection on days 7, 14 and 28 is represented in Fig. 7.b.1. Though most of the excess risk is in the first 7 days, the rate of increase remains steeper in those patients with swallowing problems on day 1.

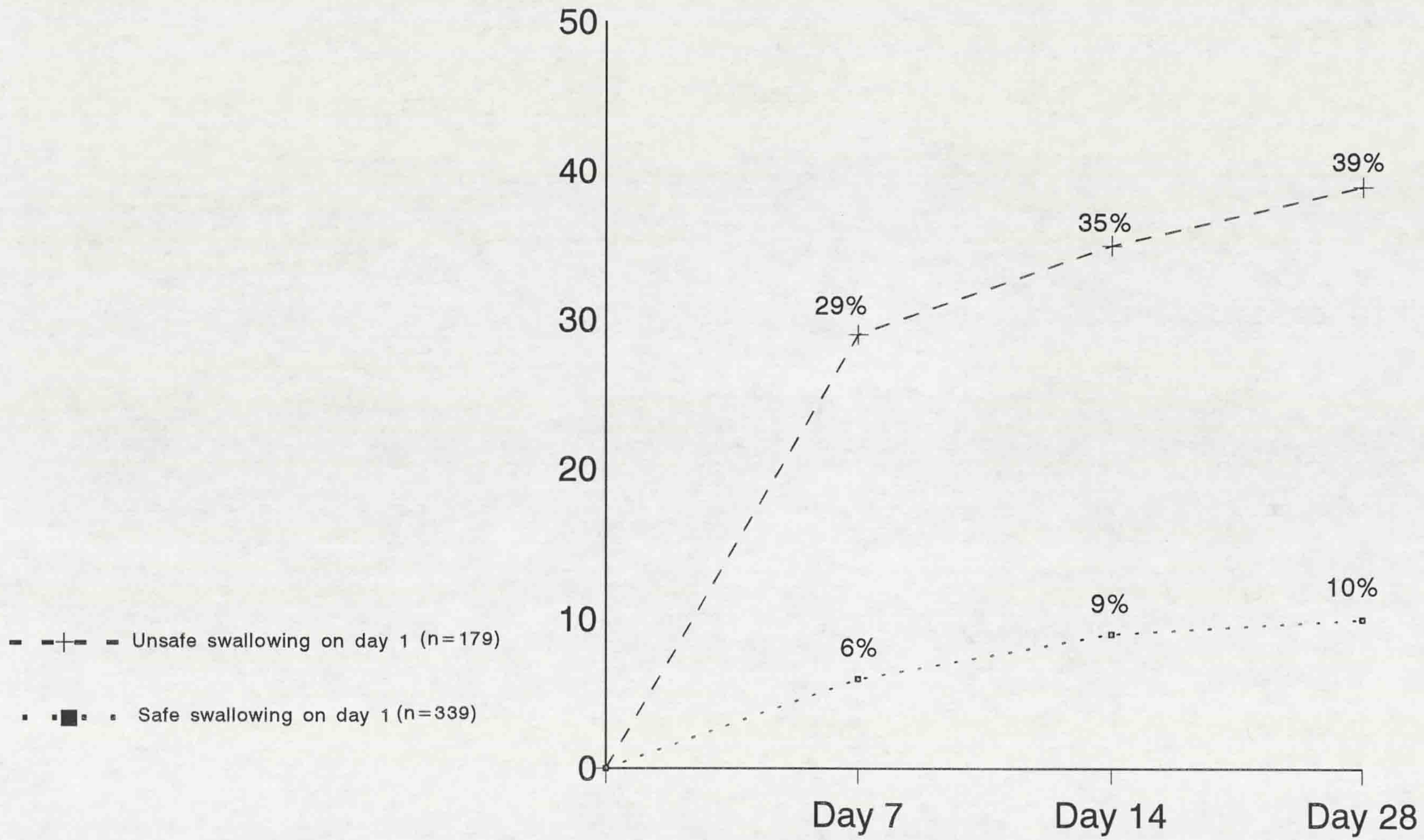
The assessment of the voluntary cough (stage I of the SSA) was a good predictor of chest infections. Patients with weak or absent voluntary cough on day 1, had a 3.5-fold increased risk (95%CI 2.4-5.1, $p < 0.01$) of developing a chest infection during hospital stay. By contrast gag reflex was a poor predictor, as patients with decreased or absent gag reflex had only a 1.5-fold increased risk (95%CI 0.9-2, $p = 0.09$) of developing a chest infection during the same period.

Table 7.b.1 Incidence of chest infection in patients whose swallowing remained unchanged, deteriorated or improved during the first 3 days.
(Patients "unassessable" by SSA on day 1 (n=112) are excluded)

	n	% chest infection* during first week	% chest infection* during hospital stay
Safe swallowing on day 1-	339	6%	10%
Possibly unsafe swallowing on day 1	71	28%	39%
Definite unsafe swallowing on day 1	108	29%	38%
Safe swallowing on day 1 -			
still safe on day 3	316	5%	9%
deteriorated by day 3**	11	18%	27%
Unsafe swallowing on day 1 -			
still unsafe on day 3	128	27%	38%
become safe by day 3	41	32%	39%

* Includes "possible" and "definite" chest infections
**ie unsafe swallowing or not assessable

Fig 7.b.1 Incidence of chest infection in patients with safe and unsafe swallowing



More chest infections occurred in patients whose swallowing deteriorated (ie from safe to unsafe or unassessable) between SSA assessments on day 1 and day 3, compared to those whose swallowing remained safe (Table 7.b.1), though this difference was not statistically significant (Fisher exact 2p= 0.13 for the 1st week and 2p= 0.08 for the whole hospital stay).

About 25% of the patients with unsafe swallowing on day 1 had recovered safe swallowing by day 3. It might be supposed that this brief period of dysphagia would carry little excess risk, but this proved not to be the case. Table 7.b.1 shows that the risk of chest infections was at least as high in the group showing early improvement as in those with more persisting problems, and over 80% of their infections occurred in the first week.

Table 7.b.2 shows the incidence and relative risks for developing a chest infection in various subgroups which themselves may be predictors of bad outcome. In the absence of other adverse factors, the incidence of chest infection was strongly associated with dysphagia, whereas in the poor prognosis groups (older patients, pre-stroke disability, severe neurological impairment at the time of onset, Total Anterior Circulation Syndrome), chest infections were common regardless of the presence or absence of swallowing problems.

Table 7.b.2 Incidence of chest infection and relative risks for developing a chest infection during hospital stay, in different subgroups.
(Patients "unassessable" by SSA on day 1 (n=112) are excluded)

	Safe Swallowing on day 1		Unsafe Swallowing on day 1		Relative Risk (95% CI)*
	n	% chest infection	n	% chest infection	
ALL	339	10%	179	39%	4 (2.7-5.8)
Age: ≤64	96	4%	31	48%	11.6 (4.2-32.4)
65-74	103	9%	64	34%	3.9 (1.9-8)
≥75	133	15%	79	41%	2.7 (1.7-4.4)
Previous disability:					
None	231	7%	100	34%	5.2 (2.3-9.2)
Mild	93	18%	57	49%	2.8 (1.7-4.6)
Severe	8	(13%)	13	39%	3.1 (0.4-22)
Conscious level (on admission):					
Alert	315	8%	128	38%	4.5 (3-7)
Drowsy	21	29%	45	42%	1.5 (0.7-3.2)
Stroke severity (on admission):					
Very severe	26	39%	70	40%	1 (0.6-1.8)
Severe	69	17%	54	41%	2.3 (1.3-4)
Moderate	112	3%	34	38%	14.3 (4.3-47.2)
Mild	131	6%	20	30%	4.5 (1.9-12.7)
OCSP Classification:					
TACS	32	38%	69	36%	1 (0.6-1.7)
PACS	158	10%	56	39%	3.9 (2.2-6.8)
LACS	70	1%	8	(25%)	18 (1.8-172)
POCS	33	3%	13	39%	12.7 (1.6-98)
Unclassifiable	46	7%	33	46%	7 (2.2-22)

*(95% Confidence intervals), (Percentages based on ≤10 cases are in brackets)

7.c LENGTH OF STAY IN HOSPITAL

Of the 564 patients, who had their swallowing assessed by the SSA on day 1, 99 (18%) died in hospital and 10 were transferred to other hospitals and were lost to follow up. In survivors (Fig 7.c.1), the mean length of stay (LOS) was 23 days longer in those with dysphagia (Kruskal-Wallis, $p<0.01$), whereas in those with dysphagia who died the LOS was 11 days shorter (Kruskal-Wallis, $p=0.07$, but $p=0.048$ for comparison of geometric means).

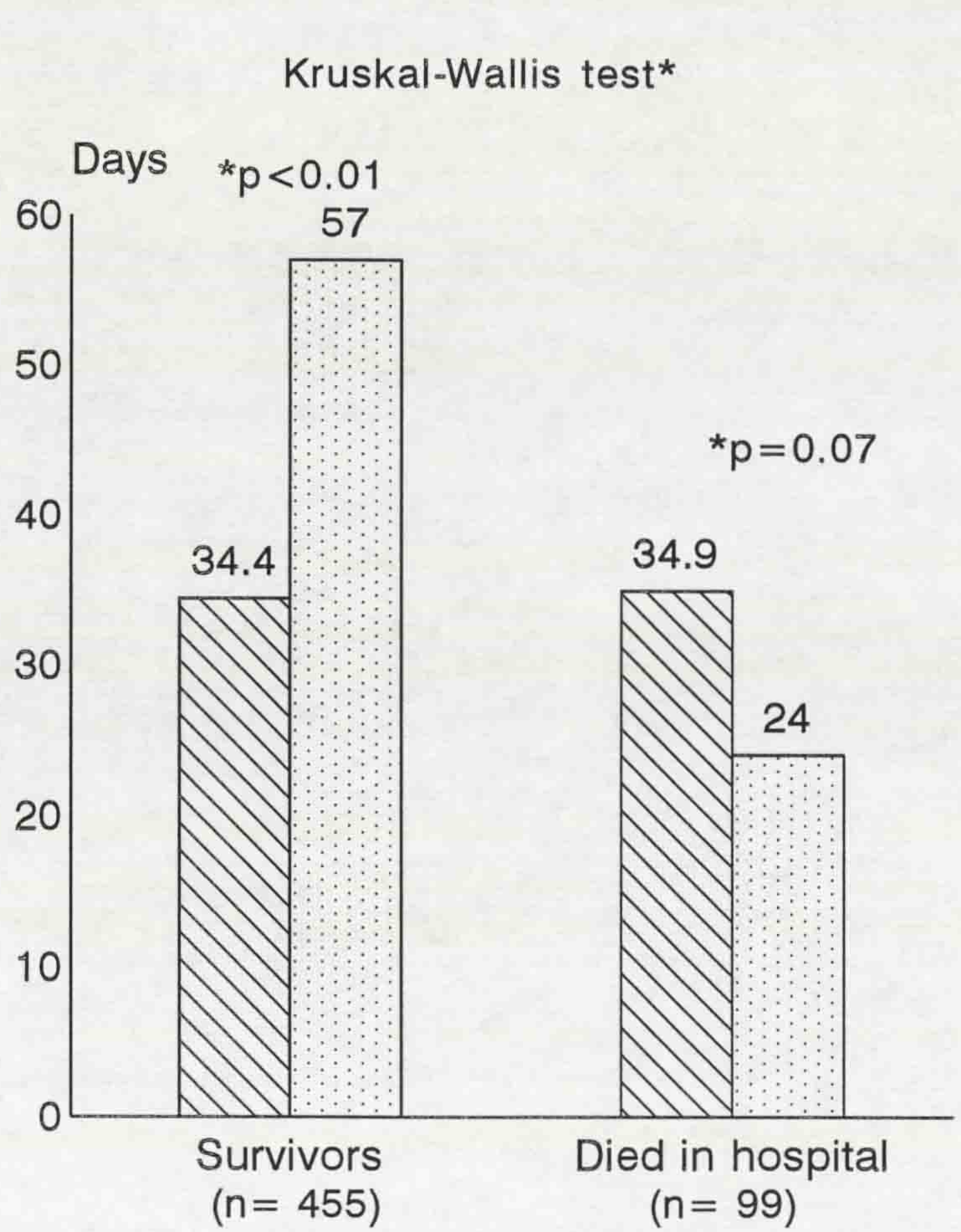
Table 7.c.1 shows that the LOS of the survivors with swallowing problems was prolonged in all subgroups, apart from those with severe pre-stroke disability, but the differences tended to be wider and statistically significant when other adverse prognostic factors were absent. Comparisons of the geometric means of LOS using one-way ANOVA, yielded significance levels similar to those shown in Table 7.c.1.

Rapid improvement of swallowing between days 1 and 3 did not appear to decrease the LOS in hospital. In 35 patients with initial dysphagia, whose swallowing became safe on day 3, the mean LOS was 52.7 days (SD 40.2), compared to 60 days (SD 50.2) for those whose swallowing remained unsafe (patients who died in hospital were excluded). A one-way ANOVA test on the arithmetic means of LOS (the group variances were homogeneous with 95% confidence) showed the difference to be non significant ($p=0.66$).

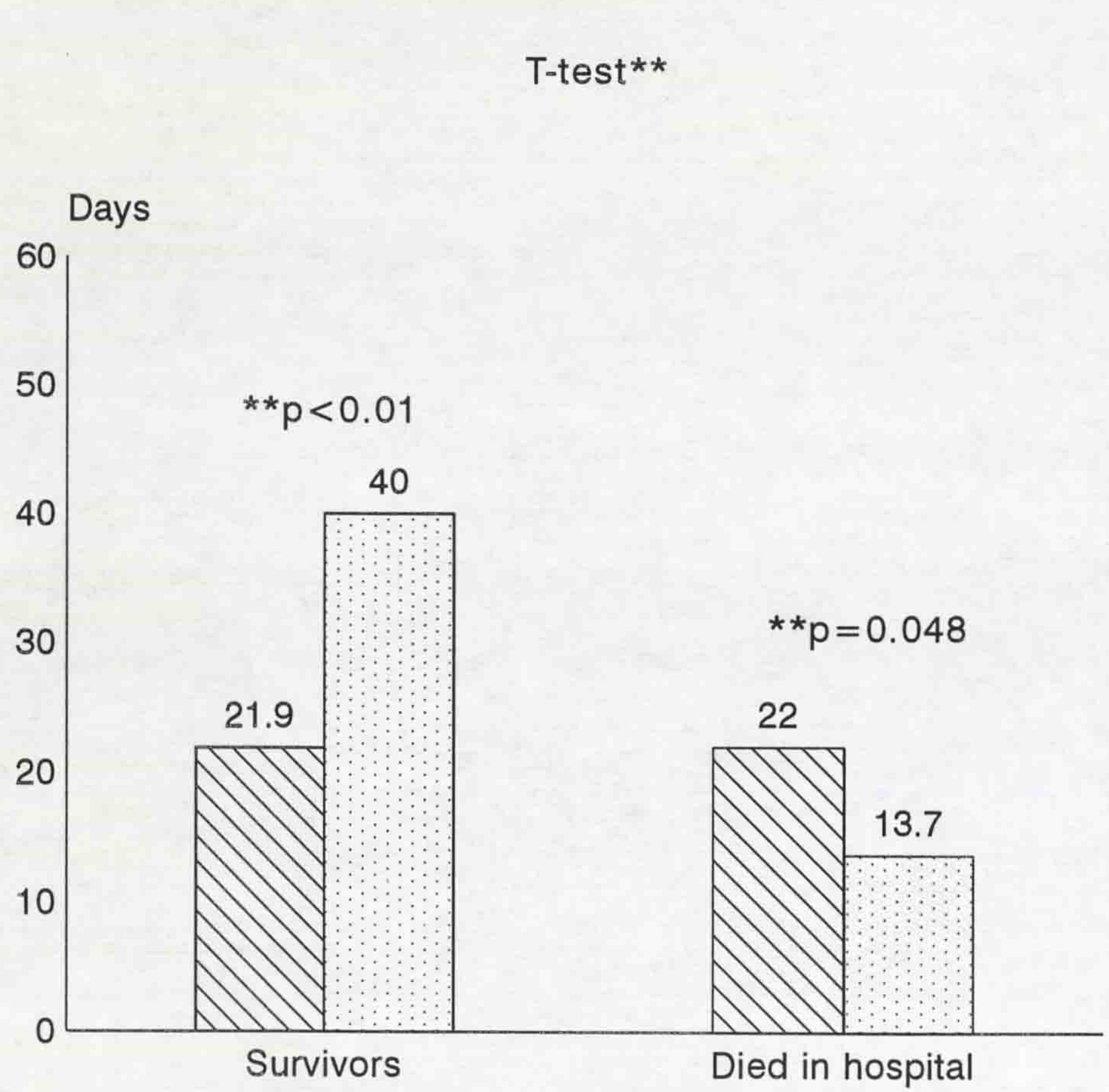
The few survivors ($n=7$) whose swallowing deteriorated during the first 3 days stayed

Fig. 7.c.1

Arithmetic means of length of stay in hospital



Geometric means of length of stay in hospital



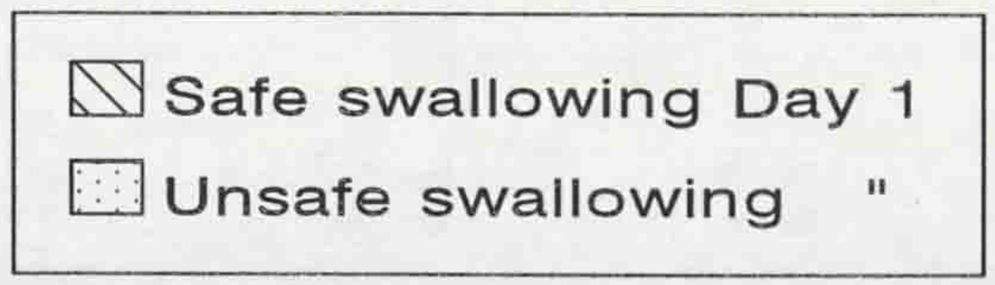


Table 7.c.1 Survivors mean length of stay (LOS) in hospital in different subgroups.

(Patients "unassessable" by SSA on day 1 (n=112), those who died in hospital (n= 99) and those transferred to other hospitals (n=10) are excluded)

	Safe swallowing on day 1		Unsafe swallowing on day 1		Differences in days
	n	Mean (SD) LOS	n	Mean (SD) LOS	
ALL	326	35.2 (41.9)	129	58.7 (47.8)	23**
Age: ≤64	99	25 (35.4)	25	73.8 (64.7)	49**
65-74	99	36.3 (42.2)	51	55.3 (43.4)	19**
≥75	127	42.2 (45)	53	54.9 (42)	13*
Previous disability:					
None	228	32.7 (37.6)	79	65.5 (54.2)	33**
Mild	90	39.2 (42.2)	39	53.8 (34.6)	15**
Severe	7	[70.7 (115)]	8	[26.6 (16.7)]	[-44]
Conscious level (on admission):					
Alert	309	33.7 (40.9)	96	55.6 (45.5)	22**
Drowsy	14	63.7 (54.3)	31	64.5 (48.8)	1
Stroke severity (on admission):					
Very severe	18	57.4 (30.6)	42	73.9 (49.3)	16
Severe	61	56.1 (44.6)	39	60.8 (47.3)	5
Moderate	109	35.6 (45.1)	29	48.4 (41.6)	13*
Mild	137	22.7 (34.1)	19	36.7 (46.1)	14
OCSP Classification:					
TACS	24	51.2 (40.3)	39	73.2 (43.5)	22*
PACS	154	35.1 (42.4)	48	51.6 (49.2)	17*
LACS	70	39.6 (52.8)	8	[50.9 (41)]	[11]
POCS	31	25.2 (22.9)	10	[42.2 (43.7)]	[17]
Unclassifiable	47	27.9 (28.6)	24	58.8 (53.2)	31**
Discharge destination:					
Private address	265	30.3 (36.1)	77	52.8 (49.2)	22**
Institution	45	56.1 (40.1)	44	60.7 (37.8)	5

* Kruskal-Wallis one way analysis of variance, p≤ 0.05, ** Kruskal-Wallis one way analysis of variance, p≤ 0.01
[values based on ≤10 cases are in brackets]

in hospital a mean of 75 days (SD 64.2). This did not differ significantly from the LOS of those with unsafe swallowing on day 1.

7.d DISCHARGE DESTINATION AND FATALITY

Death or discharge to an institution is an expected outcome of acute stroke patients in poor prognostic subgroups. This was also the case in this study, even amongst those patients well enough to have their swallowing assessed on day 1 (Table 7.d.1). In all prognostic strata, however, patients with dysphagia tended to have a higher risk of death or institutionalisation than those without swallowing problems, though the differences were not always statistically significant. In particular, the differences were smaller after stratifying for stroke severity, indicating that much of the influence of dysphagia on outcome might be due to its association with stroke severity.

Patients (n= 39) who recovered safe swallowing within the first 3 days of the stroke, were still more frequently discharged to institutions or died than those who never suffered dysphagia (p= 0.03). This difference again became non-significant after stratifying by stroke severity.

Of the 13 patients whose swallowing deteriorated by day 3, 6 died and 3 were discharged to a nursing home, indicating a prognosis similar to that of patients with unsafe swallowing at the time of stroke onset (p= 0.8).

Table 7.d.1 Discharge destination of patients in different subgroups.

(Patients "unassessable" by SSA on day 1 (n=112), and those transferred to other hospitals (n=10) are excluded)

	Safe swallowing on day 1				Unsafe swallowing on day 1				p*
	n	Home	Institution	Dead	n	Home	Institution	Dead	
ALL	343	77%	13%	10%	188	42%	23%	35%	<0.01
Age: ≤64	98	91%	6%	3%	32	66%	9%	25%	NV**
65-74	104	82%	7%	12%	66	44%	24%	32%	<0.01
≥75	140	64%	23%	13%	90	31%	28%	41%	<0.01
Previous disability:									
None	239	83%	9%	8%	103	52%	19%	29%	<0.01
Mild	93	67%	22%	12%	62	31%	31%	39%	<0.01
Severe	9	(33%)	(33%)	(33%)	16	19%	31%	50%	0.64
Conscious level (on admission):									
Alert	318	80%	12%	8%	131	47%	22%	31%	<0.01
Drowsy	22	41%	18%	41%	52	31%	27%	42%	0.62
Stroke severity (on admission):									
Very severe	30	33%	23%	43%	79	22%	29%	49%	0.44
Severe	69	67%	17%	16%	53	49%	21%	30%	0.11
Moderate	106	78%	19%	3%	36	47%	25%	28%	NV
Mild	137	91%	4%	4%	19	95%	5%	0%	NV
OCSP Classification:									
TACS	36	42%	22%	36%	75	28%	23%	49%	0.31
PACS	164	79%	13%	9%	58	57%	22%	21%	<0.01
LACS	71	86%	10%	4%	8	(63%)	(38%)	(0%)	NV
POCS	28	93%	4%	4%	12	67%	0%	33%	NV
Unclassifiable	44	77%	18%	5%	35	31%	31%	37%	<0.01

* Refers to 3x2 frequency table of Home/Institution/Dead versus swallowing safety on day 1 (X^2)

**NV= Chi-squared not valid because of low expected cell frequencies

(Percentages based on ≤10 cases are in brackets)

7.e FUNCTIONAL STATUS AT DISCHARGE

In surviving patients, functional status at discharge from hospital was measured by the Barthel index (BI). Patients who were not well enough to be assessed by the SSA on day 1 were excluded from this analysis, as well as 10 patients who were transferred to other hospitals and lost to follow up. However, of those 112 patients, whose swallowing could not be assessed on day 1, over 85% died in hospital an average of 18 days (SD 2.9) after stroke onset.

Overall, the mean Barthel score of patients with safe swallowing on day 1 was 5 points higher than those with dysphagia ($p < 0.01$). Table 7.e.1 shows that the better functional outcome in the former patients was independent of the age group, pre-stroke disability and discharge destination, though the number of survivors with severe pre-stroke disability was too small for the difference in this subgroup to be significant. Patients who were drowsy on admission had a poor outcome regardless of the presence or absence of dysphagia.

As expected, patients with more severe strokes had a poorer functional outcome, yet within each severity category, those with dysphagia still tended to achieve lower Barthel scores than those with safe swallowing. The difference in the mean scores ranged from 0.3 Barthel points in those who suffered a very severe stroke, to 2 points in those with moderate strokes and 3.4 points in those with severe strokes. Stroke severity appeared to be the major confounding factor for poor outcome, but nonetheless, dysphagia still appeared to have some independent influence.

Table 7.e.1 Mean scores on the Barthel Index (BI) in survivors at discharge from hospital, in different subgroups.
(Those "unassessable" by the SSA on day 1 (n= 112), and those transferred to other hospitals (n= 10) are excluded)

	Safe swallowing on day 1		Unsafe swallowing on day 1		
	n	Mean BI	n	Mean BI	p*
ALL	308	16.8	123	12	<0.01
Age: ≤64	96	18.2	22	13.3	<0.01
65-74	95	17.4	51	11.6	<0.01
≥75	116	15.1	50	11.9	<0.05
Previous disability:					
None	217	17.7	78	12.9	<0.01
Mild	84	15	35	12.1	<0.05
Severe	6	(9.2)	8	(4.3)	0.13
Conscious level (on admission):					
Alert	294	17.1	92	12.7	<0.01
Drowsy	11	11.3	29	10	0.64
Stroke severity (on admission):					
Very severe	18	8.4	41	7.7	0.92
Severe	57	15.1	39	11.7	<0.05
Moderate	102	17.3	25	15.3	0.12
Mild	130	18.3	18	18	0.26
OCSP Classification:					
TACS	23	12.3	38	9.8	0.20
PACS	142	16.9	45	14.4	0.07
LACS	65	18.1	6	(16.3)	0.28
POCS	31	17.6	11	15.2	0.15
Unclassifiable	47	16.3	23	8.2	<0.01
Discharge destination:					
Private address	256	17.7	73	15.1	<0.01
Institution	39	10.2	40	6.7	<0.05

* Although mean scores are shown in the Table, the Barthel scores in patients with safe or unsafe swallowing are compared using non-parametric tests (Kruskal-Wallis)
(Mean scores based on ≤10 cases are in brackets)

A similar pattern was observed within the four categories of the OCSP classification. The only subgroup showing statistically significant differences was the heterogeneous group of patients who could not be classified by the OCSP system.

Amongst all surviving patients, approximately a third had discharge BI scores of 19 or 20, a third had BI scores between 16 and 18, and the remaining third had BI scores less than 16. As can be seen at the foot of Table 7.e.2, these proportions were somewhat different in those patients who had a swallowing assessment on day 1. The same table also shows the percentage of patients in each of those functional outcome groups according to the usual prognostic factors. The results of this analysis were similar to those shown above, except that several of the chi-squared tests were not valid because of low expected cell frequencies.

The discharge BI scores of the 32 survivors with dysphagia on day 1, but who recovered safe swallowing by day 3, were lower than those of patients who never suffered dysphagia (Kruskal-Wallis p= 0.067, mean BIs 14.7 versus 16.8). The 6 patients whose swallowing deteriorated from safe on day 1 to unsafe (or unassessable) by day 3, had a mean discharge Barthel score of 10.2 points, which did not differ significantly from that of patients with unsafe swallowing on day 1 (Kruskal-Wallis p= 0.8)

Table 7.e.2 Percentage of survivors with low, medium and high total Barthel scores at discharge, in different subgroups.
(Those "unassessable" by the SSA on day 1 (n= 112), and those transferred to other hospitals (n= 10) are excluded)

	Safe swallowing on day 1				Unsafe swallowing on day 1				p*
	n	BI 0-14	BI 15-18	BI 19-20	n	BI 0-14	BI 15-18	BI 19-20	
ALL	308	18%	32%	50%	123	56%	18%	26%	<0.01
Age: ≤64	96	8%	27%	65%	22	55%	18%	27%	<0.01
65-74	95	16%	27%	57%	51	59%	20%	22%	<0.01
≥75	116	28%	38%	34%	50	54%	16%	30%	<0.01
Previous disability:									
None	217	13%	29%	59%	78	53%	17%	31%	<0.01
Mild	84	27%	42%	31%	35	51%	26%	23%	<0.05
Severe	6	(83%)	(0%)	(17%)	8	(100%)	(0%)	(0%)	NV**
Conscious level (on admission):									
Alert	294	16%	32%	52%	92	49%	21%	30%	<0.01
Drowsy	11	64%	18%	18%	29	76%	10%	14%	NV
Stroke severity (on admission):									
Very severe	18	67%	28%	6%	41	88%	10%	2%	NV
Severe	57	32%	39%	30%	39	59%	15%	26%	<0.05
Moderate	102	15%	33%	52%	25	36%	20%	44%	<0.05
Mild	130	9%	27%	65%	18	6%	39%	56%	0.56
OCSP Classification:									
TACS	23	44%	17%	39%	38	76%	13%	11%	<0.05
PACS	142	17%	38%	45%	45	36%	24%	40%	<0.05
LACS	65	11%	25%	65%	6	(17%)	(17%)	(67%)	NV
POCS	31	16%	32%	52%	11	36%	27%	36%	0.37
Unclassifiable	47	21%	28%	51%	23	83%	9%	9%	<0.01
Discharge destination:									
Private address	256	11%	32%	57%	73	37%	22%	41%	<0.01
Institution	39	67%	23%	10%	40	88%	8%	5%	NV

BI_{0-14}= Total discharge Barthel scores 0-14 (29% of the cases)
BI_{15-18}= " " " " 15-18 (28% " " ")
BI_{19-20}= " " " " 19-20 (43% " " ")

* Refers to 3x2 frequency table of low/medium/high Barthel scores versus swallowing safety on day 1
**NV= Chi-squared not valid because of low expected cell frequencies
(Percentages based on ≤10 cases are in brackets)

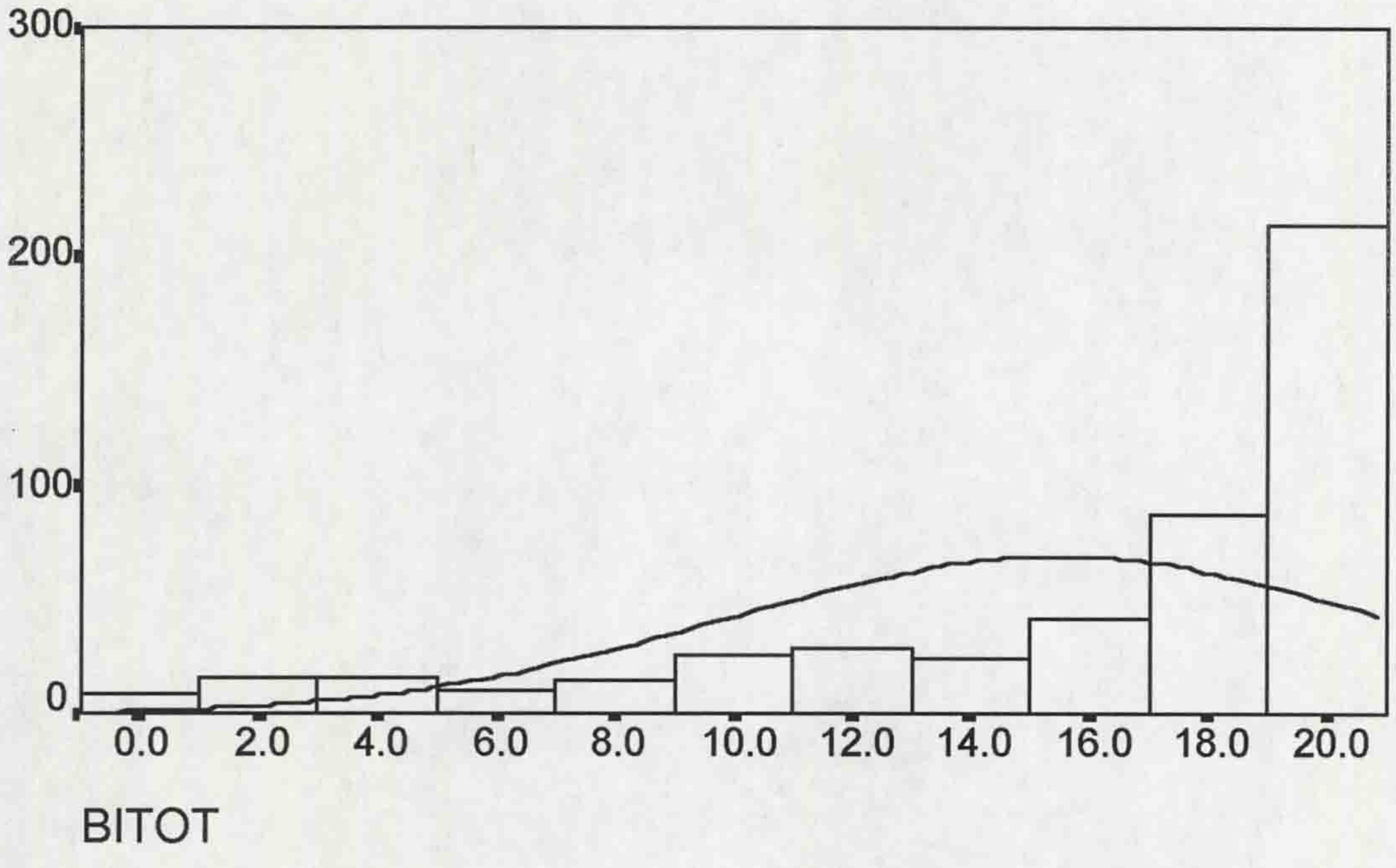
7.f DYSPHAGIA AS AN INDEPENDENT PREDICTOR OF OUTCOME

The best way to examine the independent effects of dysphagia on outcome, taking into account the effects of as many of the potential confounding variables as possible, is to use multiple linear regression (MLR) analysis. If the discharge Barthel Index (BI) score is to be used as the dependent variable in such analysis it must behave as an approximately normally distributed interval measure. As can been seen from Fig 7.f.1, the distribution of discharge BI scores is far from normal and it is debatable whether they form an equal-interval scale. Three adjustments can be made, however, which can be justified on common sense grounds and which improve the approximation to normality.

The first adjustment is to include the deaths, which must be done if the true effect of dysphagia on outcome is to be estimated. Patients who died were assigned a BI score of -10. Secondly, the "ceiling effect" of the BI is widely recognised, implying that the group of patients with a score of 20 may in fact include subjects with a wide range of higher level disability. Thus, on average the difference between patients with the maximum score and those scoring 19 should be regarded as greater than between 19 and 18, for example (ie the "ceiling" should be raised). Though the size of this interval can only be guessed, for the purposes of the MLR analysis, patients with a maximum score were reassigned to a score of 25. Finally, because the distribution was still skewed to the left, a square transformation was applied.

Although a graphic representation provides a visual basis for checking normality,

Fig. 7.f.1 Histogram of the untransformed discharge Barthel scores.



Lilliefors test, which is based on a modification of the Kolmogorov-Smirnov test, provides a statistical method to test the hypothesis that the data are normally distributed. Although the transformed scores were not normally distributed in this criterion, the residuals obtained by subtracting actual scores from those predicted by the model were normally distributed (Fig 7.f.2, Lilliefors test $p=0.2$). This indicates that one of the main conditions for validity of MLR analysis was satisfied. This condition was not satisfied by the untransformed scores (Fig 7.f.3, Lilliefors test $p < 0.01$).

Multiple linear regression analysis was performed with the adjusted BI scores as the dependent variable. Confounding factors such as stroke severity (Scandinavian Stroke Scale [SSS] on day 1), pre-stroke disability, age, conscious level on admission and SSA on day 1, were the independent variables of the MLR analysis.

The absolute value of the standardised partial regression coefficient Beta is an indicator of the relative importance of the variables, though it does not reflect their absolute importance. Table 7.f.1 shows that stroke severity (measured by SSS) was most strongly correlated with functional outcome, and that the independent contribution of dysphagia was small but still highly significant. Conscious level failed to enter in the analysis probably because this variable makes a large contribution to the SSS score.

Another way of assessing the relative importance of the independent variables is to consider the change of the squared Pearson correlation coefficient (R^2), which indicates the proportion of variance "explained" by each variable. Stroke severity explained 35 %

Fig 7.f.2 Histogram of the standardized residuals of the adjusted Barthel scores

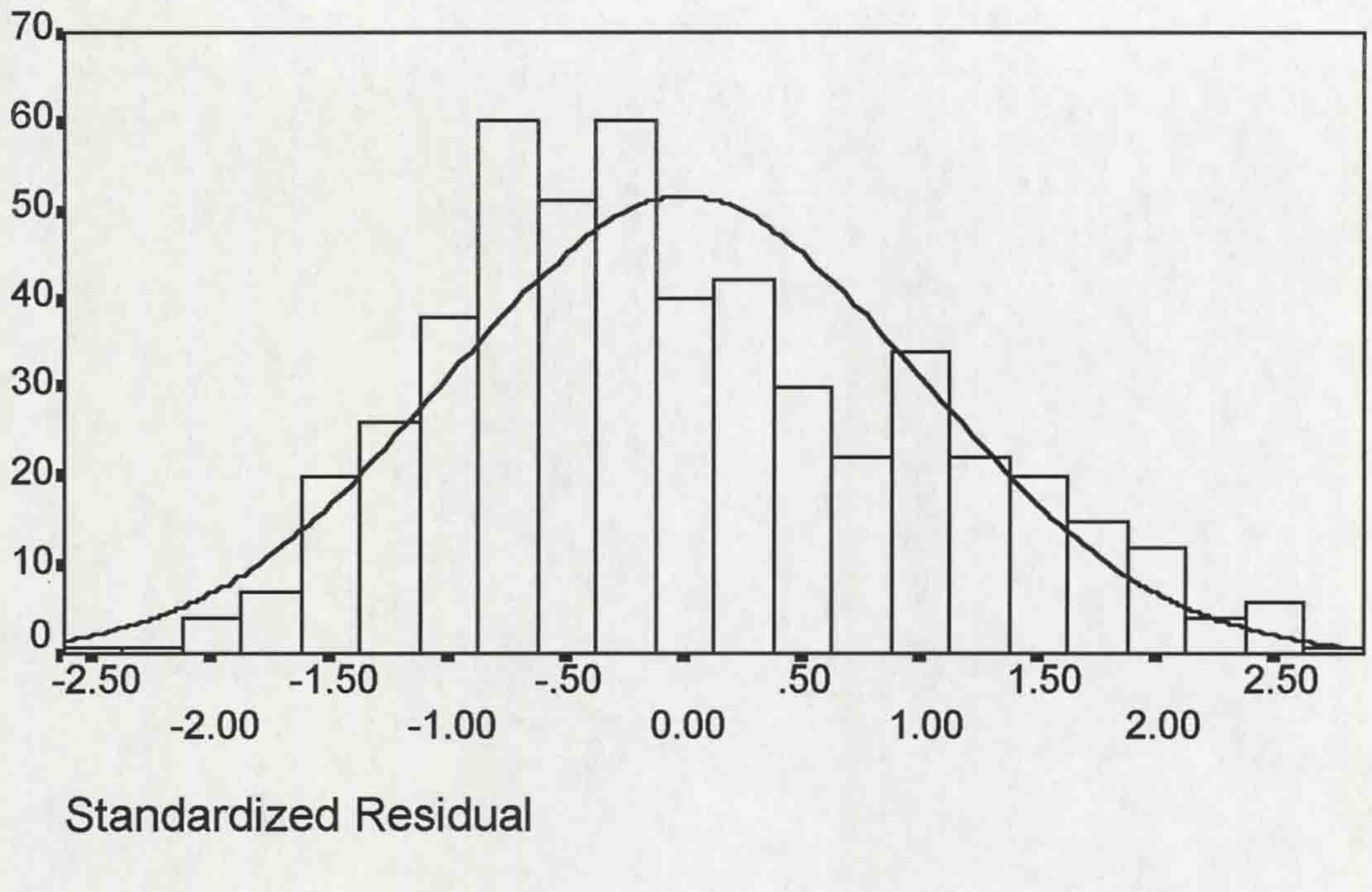


Fig 7.f.3 Histogram of the standardized residuals of the untransformed Barthel scores

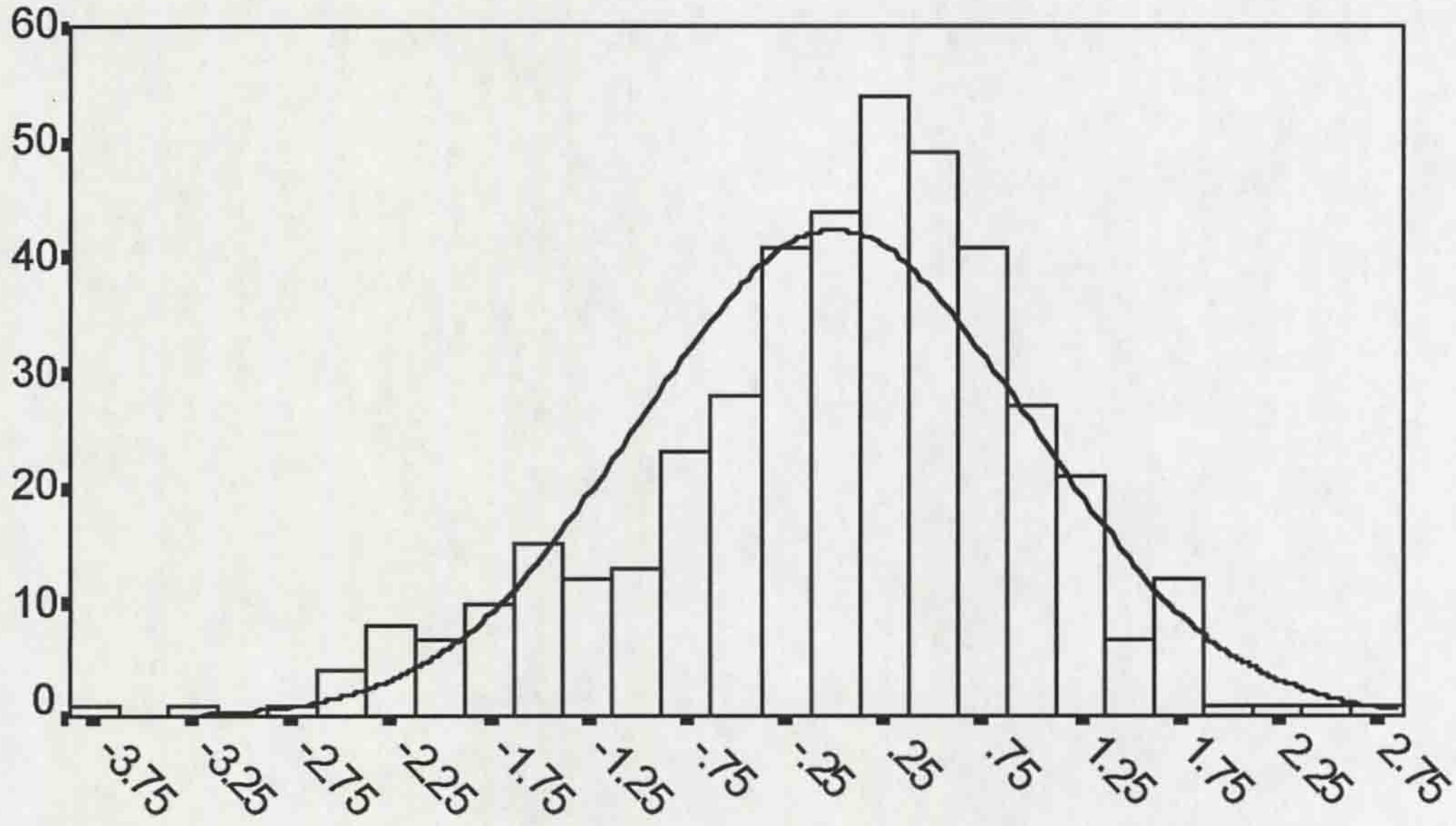


Table 7.f.1 Multiple linear regression with dependent variable the total Barthel score at discharge.
(Patients "unassessable" by SSA on day 1 (n=112), and those transferred to other hospitals (n=10) are excluded)

Independent variables:
Scandinavian Stroke Scale (SSS), Pre-stroke Rankin, Age, Conscious level, SSA

Adjusted/Transformed Barthel scores (n= 516), deaths included:

Step	Variables	Multiple R^2	Change in R^2	Beta	p
1	SSS day 1	0.35	----	0.470	<0.01
2	Age	0.41	0.06	-0.194	<0.01
3	Pre-stoke Rankin	0.44	0.03	-0.189	<0.01
4	SSA day 1	0.46	0.02	-0.132	<0.01
-	Conscious level day 1	---	---	---	0.58

Conscious level failed to enter into the analysis

"**R^2**" (coefficient of determination) is the square of the Pearson correlation coefficient
"**Beta**" is the standardised partial regression coefficient

Table 7.f.2 Multiple linear regression with dependent variable the total Barthel score at discharge.

Survivors only (n= 423)/Discharge Barthel scores not transformed:

Step	Variables	Multiple R^2	Change in R^2	Beta	p
1	SSS day 1	0.30	----	0.395	<0.01
2	Pre-stoke Rankin	0.36	0.06	-0.214	<0.01
3	Age	0.39	0.03	-0.183	<0.01
4	Conscious level day 1	0.41	0.02	-0.139	<0.01
5	SSA day 1	0.42	0.01	-0.115	<0.01

All variables were entered into the analysis

of the variance of the BI scores (Table 7.f.1), while the addition of the remaining variables in the equation explained a further 10%. The independent contribution of the SSA itself was small (2%), though statistically significant. This largely reflects the fact that most of the variation "explained" by the regression model had already been "used up" by the other variables.

To allow for this effect, dysphagia alone was entered into a linear regression analysis with BI scores as the dependent variable. In this univariate model, the SSA explained 18% of the variance.

To estimate the importance of the adjustments and transformations carried out on the BI scores, the analysis was repeated using the unadjusted scores (Table 7.f.2) The results were very similar to those in the previous table, indicating that the overall conclusions are not dependent on the technical details of the model.

7.g DISCUSSION

7.g.1 Methodological issues

The Barthel Index (BI) is a reliable [39, 65, 67, 160] and a valid measure of physical disability [157, 160]. It has been used in trials of acute stroke treatment [73, 152] as well as rehabilitation [44, 158] to detect differences in outcome between groups.

Outcome was assessed in terms of BI scores at discharge instead of at a fixed interval

after stroke onset. This can be justified on two grounds. Firstly, the functional level at discharge only reflects "stroke severity", whereas all sorts of other factors may influence function after discharge. Secondly, BI differences between groups at a fixed time after stroke are likely to be greater than at discharge (since those more severely affected are generally given longer to improve). Thus, use of discharge BI scores is likely to underestimate inter-group differences.

One of the major theoretical objections to the multiple linear regression (MLR) analysis shown above is that it assumes that the BI scores form an interval scale. In fact the weightings given to each item of the Barthel scores are arbitrary, so the level of measurement is probably ordinal at best. Furthermore, the adjustments made to include deaths and minimise the "ceiling effect" were only based on common sense grounds. In practice, though, this is the best available model and regardless of the technical details the results of the MLR analysis should be interpreted with caution.

It has been questioned whether the BI score can even be treated as an ordinal scale, as in some situations the items of the Barthel appear to split into more than one "principal component" [96]. Both factor analysis [96] and "Guttman scalogram analysis" [12], however, indicate that in stroke patients the scores do form an ordinal hierarchy.

Methodological issues on the diagnosis of chest infection have already been discussed in chapter 5.c.1.

7.g.2 Discussion of the results

The incidence of chest infection in this study (20%) was higher than that observed in some other studies which have used more restrictive diagnostic criteria. In Smithard's study [143], which used similar diagnostic criteria to the present study in a comparable population, the incidence of chest infection during hospital stay was 25%.

Poor prognosis subgroups, such as patients with a very severe stroke or drowsy on admission, but still able to be assessed by the SSA, had a high risk of developing a chest infection regardless of the presence of dysphagia. This confirms that chest infection is also a complication of severe illness with prolonged immobility, as well as often being the final event before death.

Chest infection, however, is strongly associated with dysphagia in patients without poor prognostic risk factors. Aspiration of food, saliva, and gastric contents are all potential risk factors. The findings so far have indicated that the first few days after stroke are critical for the development of complications. Over 70% of chest infections occur during the first week of stroke, and patients who recover safe swallowing by the third day after a stroke still carry an excess risk of chest infections and poor outcome.

Inpatient stroke care accounts for 7.5% of hospital bed-days and patients with dysphagia account about 40% of this total. Taking the figures from Table 7.c.1, the potential number of bed-days saved by reducing length of stay (LOS) in patients with dysphagia down to that of those with safe swallowing is 129x23=2967 or 16% of the total bed-days for stroke patients. However, dysphagia management cannot be expected

to influence stroke severity, so this effect should be allowed for. Taking the differences in mean LOS in each stroke severity category and multiplying by the number of dysphagic patients in that category (Table 7.c.1, rows 10-13) gives an adjusted total bed-days of 1510 or 8% of the total. Thus, in theory a reduction of nearly 10% of the total bed-days could be expected by efficient prevention of chest infections and malnutrition in those with dysphagia.

A high mortality is expected in patients with dysphagia, although it is partly confounded by overall stroke severity. Interventions in this group of patients may cause an increase in survival of those with very severe damage and this might have considerable financial and human cost.

Stroke severity is strongly associated with poor functional outcome. By contrast, the contribution of dysphagia to the functional outcome is relatively small, though still significant. Multilinear regression analysis, however, depends on statistical assumptions, which may not be satisfied, so although the results may be indicative, only an intervention study can show whether modification of factors related to dysphagia will affect functional outcome.

The feasibility of such a study, together with the current methods used for the detection and management of dysphagia early after stroke, is examined in the next chapter.

Chapter 8

MANAGEMENT OF DYSPHAGIA IN THE ACUTE STAGES OF STROKE

8.a AIMS AND METHODS

8.a.1 Aims

Dysphagia is a frequent event after an acute stroke and it is also associated with poor outcome (Chapters 6 & 7). Statistical models may imply that this association is independent of other confounding prognostic factors but this can only be confirmed by an intervention study. For such a study to become feasible a knowledge of the efficiency of current management of dysphagia and identification of weaknesses in detection procedures are required, so that it can be appropriately targeted. A methodological approach is also needed, which can be implemented effectively in routine practice.

In this chapter, an observational study is described, which was carried out to establish whether dysphagia is detected early after admission to hospital, and whether appropriate precautions are taken to avert preventable complications such as aspiration. Having thus established the need for intervention, a dysphagia management policy (DMP) was developed and implemented in some of the medical wards. The detection and management of dysphagia on these wards were then compared with the "conventional" management provided on the control wards.

8.a.2 Methods

Having assessed each patient using the SSA, information on current swallowing management was obtained by interviewing the patient's primary nurse, and in a large sample of cases from medical and nursing notes, as well as by observing at the bedside.

In the first 187 cases at RLUH the medical and nursing notes of each stroke patient were examined soon after the "day 3" clinical assessment. Patients who were "unassessable" on day 1, either because of reduced conscious levels, poor head control or not considered for oral feeding, were excluded. Any documentation of a formal swallowing assessment or a reference to swallowing, including the assessment of the gag reflex, was recorded from admission up to the day 3 assessment. Information on the recommended dietary management within the first 24 hours after admission was also collected. After this, only the medical notes only were examined in a further 169 cases at RLUH and 166 at BGH.

Observations at the patient's bedside were made by the investigator on day 1, in a sample of 102 cases at the RLUH, looking for written instructions on dietary management (ie "nil by mouth", semisolids only etc.), and at the fluid chart which is normally placed at the end of the bed. The use of hydration, tube feeding etc, and the positioning of any drink within reach of the patient, were also recorded.

The referrals of acute stroke patients to the SLT department at the RLUH, during a 12 month period, were also examined. The delay between admission and referral, as well

as the delay between receiving the referral and assessing the patient were estimated.

During the whole period of the study, ward staff were interviewed by the investigator soon after the "day 3" clinical assessment, and were asked about the patient's current swallowing management, without communicating the results of the SSA. Only restrictions imposed because of recognised swallowing problems were counted. These were judged either "appropriate" (SSA abnormal) or "inappropriate" (SSA normal).

After the initial results of this pre-intervention phase a dysphagia management policy was developed and introduced on some of the wards on both hospital sites. The post-intervention phase of the study is described in detail in chapter 8.d.

8.b DOCUMENTATION OF THE DYSPHAGIA MANAGEMENT

8.b.1 Documentation in the medical notes

Out of 522 medical notes of acute stroke patients well enough to be considered for feeding on day 1, none had any record of a formal swallowing assessment, though in 35 cases a glass of water was given before a management decision was taken. The only other recorded information relevant to swallowing assessment was the assessment of the gag reflex, which was tested in 44% of the cases (47% at the RLUH and 37% at BGH). In one third of these cases, the management decision was clearly based on this information (eg comments such as "no gag, patient NBM" or "no gag, refer to speech therapists"). From Table 8.b.1 it can be seen that decisions on dietary management were most likely to be clearly recorded when the gag reflex was reduced or absent, and

Table 8.b.1 Percentage of patients on restricted oral feeding as recorded in the medical notes.
(Patients who were not considered for feeding on day 1 are excluded)

		SSA on day 1	Feeding restrictions as recorded in the medical notes			
Gag reflex as recorded in the medical notes	**n**	**Unsafe swallowing n (%)**	**Free oral diet**	**Restricted oral diet**	**Restricted oral diet supplemented by intravenous fluids**	**Diet not recorded**
Present	132	48 (36%)	18%	6%	11%	64%
Reduced or absent	98	61 (62%)	5%	5%	66%	23%
Gag reflex not recorded	292	70 (24%)	4%	2%	9%	85%

the least likely, when it had not been tested.

If we assume that the gag reflex was the only information used for the detection of dysphagia, 56% of the swallowing problems in those whose gag was assessed would have been correctly identified, while 31% of those without dysphagia would have been misclassified (false positives). The relative risk of dysphagia, judged according to the SSA, was 1.7 (95% confidence intervals 1.3-2.3) when the gag reflex was impaired.

The interrater reliability of the gag reflex was tested by comparing the assessment recorded in the medical notes, with the findings of the investigator on day 1. The Cohen's Kappa was 0.29, indicating fair interobserver agreement beyond that expected by chance.

Regardless of whether any form of swallowing assessment was performed on admission, only a third of the notes contained instructions on fluid or dietary management, and in 75% of these cases involved prescribing intravenous fluids.

8.b.2 Documentation in the nursing notes

This part of the study was carried out in a smaller sample of nursing notes (n= 187) at the RLUH only, again surveying only patients who were considered for feeding on day 1.

None of the nursing notes reported any formal test of swallowing, though in a small

number of cases the assessment of the gag reflex appeared to have been copied from the medical notes. On the other hand, nursing notes were more likely to contain information on management decisions. When dietary management was prescribed in the medical notes, this was almost always (98%) also reported in the nursing notes. However, when the medical notes contained no information on swallowing management, nursing staff still recorded such decisions in their notes in 40% of cases. This was merely to confirm free oral diet, though in 12% intravenous fluids and in 6% restricted oral diet were specified.

8.b.3 Documentation of feeding instructions at the patient's bed side

This part of the study involved 102 patients at the RLUH only, all of whom were well enough to be assessed by the SSA on day 1.

Dietary instructions, clearly visible at the bedside or documented on the fluid balance chart, were found by the investigator in only 17% of the cases. Table 8.b.2 shows that of the 38 patients with unsafe swallowing (SSA day 1), 11 (29%) had documented instructions. Of the remaining 27 patients with swallowing problems and no obvious documentation, 12 were receiving intravenous fluids. It was not possible to say whether they were being given fluids or nutrition by mouth. At least 9% of the 64 patients with safe swallowing according to the SSA on day 1 were on unnecessary restrictions.

In 9 (53%) of the 17 cases where clear bedside instructions indicated that the patient should not be given fluids, drinks (ie water, coffee or tea) were nevertheless available nearby (Table 8.b.3). In 5 of these they were clearly within the patient's reach.

Table 8.b.2 Documentation of feeding restrictions.
(Patients who were not considered for feeding on day 1 are excluded)

		Feeding restriction documented*		Feeding restriction NOT documented	
	n	Restricted oral feeding	Nil by mouth Intravenous infusion	? Restricted/ ?Free oral diet No Intravenous infusion	? Restricted/ ?Free oral diet Intravenous infusion
Safe swallowing on day 1	64	4 (6%)	2 (3%)	52 (81%)	6 (9%)
Unsafe swallowing on day 1**	38	2 (5%)	9 (24%)	14 (38%)	12 (32%)

* Documentation visible by the patient's bed side, in the fluid chart or both
** One patient admitted with a gastrostomy tube was excluded

Table 8.b.3 Availability of drinks by the patient's bedside.
(Patients who were not considered for feeding on day 1 are excluded)

	Drinks by the patient's bed side				SSA on day 1
	n	Not available	Out of patient's reach	Within patient's reach	Unsafe swallowing
Feeding restriction documented*	17	8 (47%)	4 (24%)	5 (29%)	11 (65%)
Feeding restriction NOT documented	85	9 (11%)	20 (24%)	56 (66%)	27 (32%)

* In all cases this involved restricting or forbidding oral (unthickened) fluids

8.b.4 Referrals to speech and language therapists

During a 12 month period, of the 172 patients included in the study at RLUH, 48% were referred to SLTs for assessment of swallowing, communication, or both by the patient's medical team.

Of the 90 patients who were not referred for a SLT assessment, 20 were not well enough to be considered for feeding and 15 (17%) had some degree of swallowing problems (SSA on day 1). None of these patients were referred at any stage during their hospital stay, although none had recovered safe swallowing by the end of the first week.

Table 8.b.4 shows that of those 54 patients, who were referred to SLTs for dysphagia assessment (with or without communication assessment), 16 (30%) had had no swallowing problems when assessed by the investigator using the SSA on day 1. A further 28 patients were referred for communication assessment only, yet 4 (14%) of these had dysphagia according to the SSA on day 1.

Once swallowing problems were detected by the ward staff, the referral reached the SLT department fairly quickly, even in those who were not well enough to be assessed immediately (Table 8.b.4). The SLT response was also prompt, and most of the patients who needed immediate attention were seen within 1 to 2 days after the referral was received. However, the delay between admission to hospital and specialist assessment in most of the cases amounted to 3-4 days.

Table 8.b.4 Patients referred to speech and language therapists (SLT) during a 12 month period.
(All study population (n= 172) is included)

	n	Safe swallowing (SSA on day 1)	Unsafe swallowing (SSA on day 1)	Unassessable on day 1
Referred for swallowing assessment*	54	16 (30%)	30 (56%)	8 (15%)
Median delay in days from admission to referral		1	1	2
Median delay in days from referral to be seen by SLT		1	1	1
Referred for communication assessment only	28	23 (82%)	4 (14%)	1 (4%)
Median delay in days from admission to referral		1	1	3
Median delay in days from referral to be seen by SLT		1	2	7
Not referred to SLT	90	55 (61%)	15 (17%)	20 (22%)

* Includes patients referred for both swallowing and communication assessments

8.c AUDIT OF ACTUAL DYSPHAGIA MANAGEMENT

The pre-intervention phase involved 273 patients at the RLUH and 106 at BGH. Patients not able to be assessed on day 1 by the SSA were excluded. The proportion of patients with dysphagia did not differ between hospitals (p= 0.4), and overall 34% of the patients, who could be assessed by the SSA on day 1, had swallowing problems.

Initially the findings of the SSA on day 1 were compared with the feeding restrictions, which were being applied on day 3 (Table 8.c.1). Of the 252 patients who had safe swallowing on day 1, 11% were on unnecessary restrictions, whereas of the 127 patients with unsafe swallowing, 46% had no apparent precautions taken against aspiration. The proportion in whom feeding restrictions were applied, did not differ between hospitals.

Similar results were obtained when the SSA on day 3 was compared with the feeding dietary restrictions applied on the same day (Table 8.c.2). However, a slightly smaller proportion (40%) of those at risk of aspiration were on unrestricted oral diet.

During this preliminary phase of the study, 19% of patients, who were well enough to be assessed on day 1, suffered at least one episode of chest infection. Patients with dysphagia had a 5-fold higher risk of developing a chest infection compared to those without swallowing problems, although the relative risk was considerably smaller at BGH (2.3 [95%CI 1.2-4.6] versus 7.1 [95%CI 2.4-11] at RLUH).

Table 8.c.1 **Pre-intervention phase**: Comparison of the SSA on day 1 with oral feeding restrictions at day 3.
(Patients who were not considered for feeding on day 1 are excluded)

		Feeding restrictions on day 3		Chest infections during hospital stay
SSA on day 1	**n**	**% Restricted diet**	**% Free diet**	**% Chest infection**
RLUH:				
Safe swallowing	185	12%	88%	6%
Unsafe swallowing	88	55%	45%	42%
BGH:				
Safe swallowing	67	8%	92%	16%
Unsafe swallowing	39	54%	46%	39%
Combined hospitals:				
Safe swallowing	252	11%	89%	8%
Unsafe swallowing	127	54%	46%	42%

Table 8.c.2 **Pre-intervention phase**: Comparison of the SSA on day 3 with oral feeding restrictions at the same day.
(Patients who were not considered for feeding on day 1 are excluded)

		Feeding restrictions on day 3	
SSA on day 3	**n**	**% Restricted diet**	**% Free diet**
RLUH:			
Safe swallowing	200	13%	87%
Unsafe swallowing	56	63%	38%
BGH:			
Safe swallowing	61	7%	93%
Unsafe swallowing	26	54%	46%
Combined hospitals:			
Safe swallowing	261	12%	89%
Unsafe swallowing	82	60%	40%

8.d DYSPHAGIA MANAGEMENT POLICY

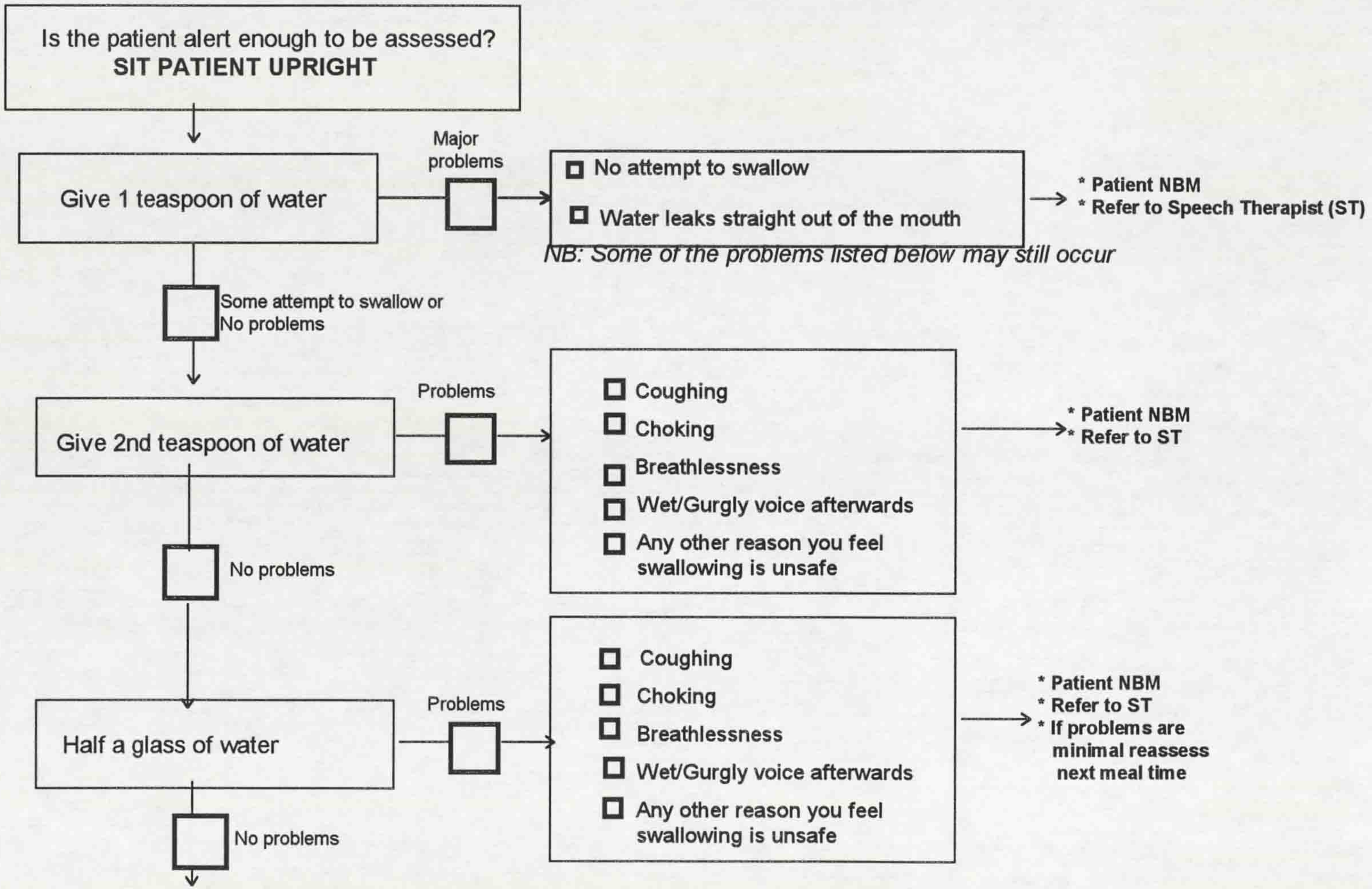
The dysphagia management policy (DMP) was developed in collaboration with senior nursing staff and SLTs and was implemented on two wards at the RLUH and on one ward at BGH. These "intervention wards" were chosen mainly on the grounds that the physicians responsible were willing to participate, although a random selection would have been preferred. After the physicians' agreement, the nursing managers were involved and then a training period followed.

All qualified nurses on the intervention wards (except the night staff on the only ward without internal rotation of staff) had a short theoretical and practical course on dysphagia over a period of two months. The aim was to increase awareness of swallowing problems and to encourage nurses to assess all stroke patients, using a simplified version of the SSA (Figure 8.d.1), as soon as possible after admission, before any food or drink was given.

The simplified SSA was designed to be a step by step procedure, keeping the most important items of the original SSA. Most of stage I SSA items were excluded because abnormalities occurred only rarely, and therefore they were insensitive as detectors of dysphagia. Although the voluntary cough alone is sensitive enough to be used as a screening assessment in some circumstances, in this study it was thought best for practical reasons to encourage the ward staff to assess swallowing directly.

The simplified SSA was also designed to ensure maximum safety for patients. If any

FIG 8.d.1 **DYSPHAGIA SCREENING TEST / *STAFF SWALLOWING ASSESSMENT (SSA)***



* **If OK → Free diet/fluids. Observe patient eating solid food.**
* **Always make sure patients are sat well up before attempt to feed.**
* **Check again with a glass of water before next meal.**
* **Repeat assessment if patient deteriorates.**

problems were found, however small, nursing staff were instructed to keep the patients "nil by mouth" and refer immediately to SLTs. Patients usually received intravenous fluids until a decision was made by senior doctors, together with SLTs, whether oral feeding could be resumed. When nursing staff felt at the first assessment that swallowing was safe, free oral diet was allowed. These patients were re-assessed once again before the next meal, as well as being informally watched during feeding or drinking for any sign of discomfort.

The routine practice of dysphagia management on the remaining wards was not altered, and they, therefore acted as "control wards". There is no rotation of nursing staff between wards so apart from on call doctors, inter-ward "contamination" was minimal.

A similar dysphagia course for junior doctors was attempted, but it proved almost impossible to detach doctors from their clinical duties. Thus a ward policy was written and signed by the ward consultants, explaining the nurses' role in this intervention and requiring full written justification for any alteration of their swallowing management decisions. An information leaflet was given to patients and carers explaining the nature of dysphagia and the need for any feeding.

8.e RE-AUDIT OF ACTUAL DYSPHAGIA MANAGEMENT

During the post-intervention phase 117 patients were assessed by the SSA on day 1 on the control wards and 44 on the intervention wards. Patients not well enough to be

assessed on day 1 were excluded. The proportion of patients with dysphagia on the intervention wards was considerably higher than that on the control wards (61% versus 29% respectively) and than the overall proportion during the pre-intervention phase (35%). Intervention and control wards did not differ in the proportion of patients who had unsafe swallowing on day 1, but had recovered safe swallowing by day 3 (Fisher exact 2p= 1).

Table 8.e.1 shows that of those who had unsafe swallowing on day 1, 22% were on unrestricted oral feeding on the intervention wards, whereas there was no change on the control wards (47%). By contrast, of those who had no swallowing problems, 24% had apparently unnecessary restrictions on the intervention wards compared to 15% on the control wards (and 11% in the pre-intervention audit: Table 8.c.1).

The SSA on day 3 was also compared with the feeding restrictions at the same day (Table 8.e.2). As can be seen, a smaller proportion of patients with unsafe swallowing were on inappropriate oral feeding on the intervention wards, whereas there was no difference on the control wards.

Overall, the precautions taken on the intervention wards were increased, mostly in those who were at risk of aspiration, but also in some of those who had safe swallowing. There was little change in the proportion of patients without swallowing problems having unnecessary restrictions in the control wards:from 11% to 15% using SSA on day1, and from 12% to 17% using the day 3 swallowing assessment.

Table 8.e.1 **Post-intervention phase**: Comparison of the SSA on day 1 with oral feeding restrictions at day 3.
(Patients who were not considered for feeding on day 1 are excluded)

		Feeding restrictions on day 3		Chest infections during hospital stay
SSA on day 1	**n**	**% Restricted diet**	**% Free diet**	**% Chest infection**
Intervention wards:				
Safe swallowing	17	24%	77%	6%
Unsafe swallowing	27	78%	22%	15%
Control wards:				
Safe swallowing	83	15%	85%	16%
Unsafe swallowing	34	53%	47%	44%

Table 8.e.2 **Post-intervention phase**: Comparison of the SSA on day 3 with oral feeding restrictions at the same day.
(Patients who were not considered for feeding on day 1 are excluded)

		Feeding restrictions on day 3	
SSA on day 3	**n**	**% Restricted diet**	**% Free diet**
Intervention wards:			
Safe swallowing	21	24%	76%
Unsafe swallowing	20	85%	15%
Control wards:			
Safe swallowing	83	17%	83%
Unsafe swallowing	29	52%	48%

The incidence of chest infections during hospital stay on the intervention wards was low (11%), despite the higher proportion of patients with dysphagia and with "severe strokes" (SSS<33: 61% versus 44%). On the other hand, the incidence of chest infections on the control wards was even higher (24%) than it had been during the pre-intervention phase (19%).

The incidence of chest infection did not differ between patients with or without dysphagia (Fisher's exact 2p= 0.63) on the intervention wards, whereas on the control wards, patients with swallowing problems developed significantly more chest infections compared to those without swallowing problems ($p < 0.01$). However, these results should be taken cautiously as the numbers were very small and bias or cross-contamination can not be excluded.

8.f DISCUSSION

8.f.1 Methodological issues

The intervention part of this study was planned to explore the feasibility of a larger multicentre study. It was designed as a "before and after" intervention audit and not as a randomised controlled trial. This methodology was the best available model applicable in the local setting. Although the presence of the investigator might have influenced the ward staff to modify their management, the length of the study may have attenuated this factor. The management before and after the intervention did not change significantly on the control wards, thus supporting the above hypothesis.

The experience gained so far contributes to the discussion of methodological strategies for studies of this kind. Three alternative methodological options, which could have been taken, will now be briefly discussed.

The first option would be to *randomise patients on the same ward for DMP or routine management*. Although this would be methodologically correct, it is unlikely that the ward staff could provide two distinct patterns of care to patients on the same ward. Intra-ward "contamination" could be avoided, however, if the ward staff were not involved in the detection of dysphagia and the initial assessment was performed by a small team of trained staff nurses covering the whole hospital. This would be undesirable, however, as it would deprive ward staff of responsibility for care of their own patients.

The second option would be to *randomise the wards in which the DMP would be implemented*. This is feasible, although inter-ward "contamination" is still possible. Innovative management is likely to be adopted by staff on all wards, even while still under evaluation.

The third option would be to *randomise the hospitals in which the DMP would be implemented*. Because of differences in the catchment population, and admission policies between hospitals individual patients cannot be said to differ only by chance. The way to avoid this problem would be to randomise enormous numbers of hospitals, which would be impractical. Thus, the "before and after" intervention audit may still be the best pragmatic option to be taken in future studies.

Another methodological issue of this study is the choice taken to compare the SSA on day 1 and 3 with feeding restrictions on day 3. Ideally, each patient should be continuously observed for the first three days to establish with precision what feeding restrictions were taken and whether the patient adhered to them.

Interviewing the primary nurse was the practical solution. By the third day after the stroke, ward staff should have had enough time to detect swallowing problems and take the appropriate precautions. Using the SSA on both day 1 and day 3 allowed for possible delays in detecting changes of swallowing ability, by ward staff.

Medical and nursing notes were not checked after the implementation of the DMP, because on the intervention wards they were using specially developed swallowing assessment forms.

8.f.2 Discussion of the results

The audit of the medical and nursing notes showed that no formal swallowing assessment was used to detect dysphagia in stroke patients. Although it was documented in under half of the cases, it appeared that doctors were sometimes basing feeding management decisions on the gag reflex. On the whole, however, doctors appeared to be more concerned with prescribing intravenous fluids for hydration than with identifying swallowing problems.

By contrast, nursing staff were better at recording feeding management, even if only

to denote normal diet. Feeding restrictions appeared to be implemented informally (eg by oral instruction) as only a very small proportion of patients had written documentation by the bedside. Even when instructions forbidding oral fluid intake were visible, a glass of water was often still within the patient's reach.

Overall, decisions on feeding appeared to be left to the judgement of nurses, at least until an SLT assessment was carried out. This conforms with the more "traditional" role of nurses, but the DMP attempted to extend this role to provide a more efficient and flexible pattern of interdisciplinary care for acute stroke patients.

The DMP also attempted to improve the appropriateness of speech therapy referrals. The results of this study showed that the ward staff referred 17% of patients with safe swallowing and 30% of patients with unsafe swallowing to SLTs. Nearly one third of those referred for SLT swallowing assessment in fact had safe swallowing, whereas many patients with dysphagia did not receive specialist assessment.

The implementation of the DMP clearly showed that the detection and management of dysphagia can be improved. More patients at risk of aspiration had precautions taken, though more patients with safe swallowing were unnecessarily restricted. The latter effect was also seen to a lesser extent on the control wards. Possibly the ward staff on the control wards were aware of the dysphagia project and tried to improve management, but without having the necessary training.

The proportion of patients with swallowing problems on the intervention wards was

surprisingly high, and there was no difference between the two hospitals (65% at RLUH versus 54% at BGH, Yates corrected p= 0.75). This may partly be explained by differences in the severity of stroke together with the small number of patients on the intervention wards. On the control ward 44% of the patients were admitted with a severe or very severe stroke compared to 61% of those on the intervention wards (p= 0.03 for 3-category comparison). It is unlikely that the investigators modified their assessment after having already used it over one thousand times.

This study was not designed to detect changes in outcome, therefore assessment of the possible effects of DMP in reducing the incidence of chest infection or improving functional outcome must await future studies.

Successful implementation of any DMP must include continuation after the end of the period. Experience in Liverpool suggested that dysphagia management on the intervention wards gradually returned to the previous informal routine. An ongoing training programme is needed so that a critical mass of SSA users is established and new staff are introduced to the DMP.

Chapter 9

CONCLUSIONS

9.a CONCLUSIONS OF THE STUDY

9.a.1 The Standardised Swallowing Assessment (SSA)

The SSA has been developed to detect dysphagia in acute stroke. It is safe, as the 3-stage design allows the assessor to stop, if at any stage it is felt unsafe to continue. The SSA can be carried out in a few minutes by non-specialists at the bedside, and, if necessary, can be frequently repeated.

The comparison of the SSA with videofluoroscopy (VFS), the conventional "gold standard" for studying dysphagia, showed that the SSA was fairly accurate. The VFS, however, remains the most sensitive investigation for the detection of aspiration, although the significance of small amounts of aspiration for the development of complications has still to be established. In this study, the overall judgment of swallowing safety, based on the SSA, was a better predictor of chest infections than aspiration during VFS.

The association of dysphagia, detected by SSA, with increased risk of developing chest infections and poorer functional outcome, was confirmed in the larger "natural history study", providing further evidence for the validity of the SSA. These associations are confounded by stroke severity, but multivariate analysis suggested that dysphagia has a significant independent effect on outcome.

Preliminary interobserver reliability studies showed moderate agreement between raters using the SSA, although prior training may improve interobserver agreement. This hypothesis has been examined in a more recent study, described in Appendix A.

9.a.2 Other methods of detecting dysphagia

The gag reflex often appears to be used instead of a clinical swallowing assessment for detecting patients at risk of aspiration. The results of this study showed that there was a weak association between gag reflex and dysphagia detected by the SSA. The gag reflex was also a poor predictor of chest infection, and thus it is of little or no use in the detection and management of dysphagia.

By contrast, voluntary cough, in certain circumstances, could be used as a preliminary screening assessment. This is justified because of its strong association with the overall SSA and its value in predicting chest infections.

Milk nasendoscopy did not perform any better than the SSA in detecting patients at risk of aspiration and cannot replace VFS. On the other hand, although VFS is now available in many British hospitals, and provides detailed information on swallowing abnormalities, most patients cannot be investigated soon after the stroke. Even if this was feasible, it would be virtually impossible to repeat at will, so oral feeding decisions would have to be taken on the evidence of only a few swallows.

9.a.3 Incidence and Course of Dysphagia

This study confirmed that dysphagia is a frequent occurrence after an acute stroke. Over one third of patients, admitted to hospital early after a stroke, and well enough to have their swallowing assessed, were found to have some degree of swallowing impairment. Patients in the poor prognostic subgroups (ie older age, drowsy, with a "severe stroke", or with TACS) had the highest incidence of swallowing problems. Even among those without these risk factors, over 10% still had dysphagia.

In those who survived, dysphagia often improved during the first few days, so that by the end of the first fortnight about half of the patients had recovered safe swallowing. About 10% had persistent swallowing problems lasting over a month, and so required long term management.

9.a.4 Dysphagia and outcome

Dysphagia was associated with increased morbidity and mortality. Dysphagic patients who survived the stroke, stayed longer in hospital and were more likely to be discharged to an institution than those with no swallowing problems. A large proportion of chest infections occurred during the first week after stroke, indicating that preventative measures and interventions should focus on this period.

The relationship of dysphagia with worse outcome, however, was confounded by the effects of stroke severity. Multiple linear regression analysis showed that although dysphagia could explain only a small percentage of the variation of Barthel scores at

discharge, it was still an independent predictor of poor outcome.

Patients who were dysphagic on admission, but recovered safe swallowing during the fist few days, still had an increased risk of chest infections and poor outcome compared to those without swallowing impairment. Whether early detection of dysphagia and appropriate feeding restrictions might improve outcome in these patients should be examined by a future study.

9.a.5 Management of dysphagia

The use of the SSA allowed the routine management of dysphagia in the two Liverpool hospitals to be audited. Dysphagia is often missed and appropriate precautions not taken to protect patients at risk of aspiration. Speech and language therapists respond fairly quickly to referrals, but it still takes 2 to 3 days for many patients to be receive a specialist swallowing assessment.

The Dysphagia Management Policy (DMP), which was developed in collaboration with nurses, SLTs and doctors, was successfully implemented on three intervention wards. In these wards, the management of dysphagia improved, although the proportion of inappropriate feeding restrictions was increased. On the control wards, there was little overall change.

Although the implementation of DMP was shown to be feasible, this study was not designed to detect any effects on the development of complications or on functional outcome.

9.b NEED FOR FUTURE RESEARCH

This study has raised many key questions which remain to be answered by further research.

Firstly, although the SSA has shown to be useful and reliable, it may not be necessary in every case. The possibility of using even simpler assessments, such as "head control" or "voluntary cough" in some circumstances, should be evaluated.

Secondly, better methods of assessing swallowing might be developed, which can be used at the bedside. Possibilities range from use of the stethoscope to auscultate over the larynx during swallowing to more complex electromyographic techniques.

Thirdly, the possibility of introducing materials of different consistencies during the dysphagia screening assessment should be considered, and much work remains to be done on the nutritional consequences of dysphagia.

The role of instrumental techniques, such as VFS and milk nasendoscopy need to be better defined. In particular more data are needed on whether small amounts of aspiration seen at VFS are of any clinical significance and require a change in management.

The possible importance of continual aspiration of gastric contents or secretions, other than during feeding, needs to be established. Monitoring of inter-tracheal acidity and

arterial oxygen saturation after stroke provide means of assessing gastric regurgitation and aspiration.

Finally, it still remain to be seen whether adequate precautions taken early after stroke can prevent the development of chest infections and improve outcome. Shortening the length of stay in hospital and speeding functional recovery after stroke are beneficial for both patients and the Health Service. On the other hand, the implementation of policies, which may appeal to common sense, but whose effectiveness is as yet unknown may increase costs (eg generating extra referrals to SLTs).

A multicentre randomised controlled trial of a Dysphagia Management Policy is probably impractical for the reasons discussed above. A large "before and after" audit study, with sufficient numbers to estimate the effects of the DMP on outcome, is the next best option. Such study is already underway, involving 7 large British hospitals, and the initial pre-intervention audit has already been concluded. Dysphagia Management Policies are being developed, which are based on common core principles, but which respect local needs in individual centres. The next step will be to measure the effects of the implementation of these policies on patient outcome.

Appendix A

FURTHER INTEROBSERVER RELIABILITY STUDIES

A.1 AIMS AND METHODS

The first interobserver study (Chapter 4.e) was carried out without prior training for the SSA. Furthermore, the investigators during the first study had performed separate assessments, and thus did not observe the same clinical signs. A further study was, therefore, planned to investigate whether agreement on the definitions of each item of the SSA and some practical experience could improve interobserver agreement.

This interobserver study was organised by the author at the end of 1995 and was carried out at Aintree Hospitals in Liverpool.

A two day theoretical and practical training course was held prior to the study. The theoretical part consisted of lectures on the physiopathology of deglutition and aspiration given by a speech and language therapist. The practical part of the course aimed to standardise the assessment by practising scoring the SSA using videorecordings of patients, as well as assessing stroke patients on the wards. Areas of uncertainty were discussed and a standard practice was agreed.

This study involved four nurses who had participated in the whole training course ("T"), one nurse and one nutritionist, who only attended the one day practical part of the course ("PT") and 2 more research nurses, who had not taken part in the training

("NT") but were generally experienced in the assessment of stroke patients including swallowing assessments. The raters were divided into two groups of four (A & B). Raters "NT" were participating in group A and raters "PT" in group B.

A total of 18 acute stroke patients were assessed, 9 by each group, with one rater performing the SSA and the other 3 observing. After giving each spoonful of water, all raters independently recorded their judgment on whether it was safe to carry on with the assessment. If all raters agreed that swallowing was unsafe the SSA was discontinued.

The assessor conveyed the findings of two items of the SSA stage II ("laryngeal movement" and "repeated laryngeal movement"), which cannot be scored by observation only. In all the other cases ratings were recorded without conferring. The assessments of breathing pattern, tongue and palate movements had not been included in this study, whereas the assessment of pharyngeal sensation was introduced.

Agreement between each pair of raters was measured using the Cohen's Kappa (K) [37]. K values between raters "T" were computed using the mean of the observed and expected agreement, as this group was composed of four raters. Agreement between groups of raters was measured using Kappa for polychotomous data and more than two raters [17, 95]. The K values indicated poor, fair, moderate, good, and very good agreement using the same criteria as in Chapter 4.e.2.

A.2. RESULTS

Initially, the agreement between the four raters in each group was measured (Table A.1). Overall, group B, in which all raters had some training, performed better than group A. Agreement, however, in certain items such as head control, weak voice and voice quality, was consistently very poor to moderate in both groups. A "perfect" agreement (K= 1) was expected for the items (laryngeal movement and repeated laryngeal movement) in which assessor's opinion was disclosed to the observers. This was not the case, as in group A the polychotomous K was less than 1.

Agreement on overall swallowing safety is of primary importance as clinical decisions depend upon it and good (K= 0.64) to very good agreement (K= 0.9) beyond chance was achieved on the overall SSA in both groups of raters.

Finally, the agreement of raters with a similar degree of training was compared. Table A.2 shows that agreement in some items appeared to improve with training (eg voice quality, coughing), while in others (eg head control, lips movement) it did not. Agreement on the overall safety of swallowing was good between all raters, although raters with some training performed better.

A.3 DISCUSSION AND CONCLUSIONS

The design of this study was somewhat different from that of the first interobserver

Table A.1 SSA: Interobserver agreement between four raters in each group.
[Polychotomous Kappa (K) with 95% CI and Proportion of Observed (Pobs) and Expected (Pexp) agreement]

	GROUP A				GROUP B			
SSA	**K**	**95%CI**	**Pobs**	**Pexp**	**K**	**95%CI**	**Pobs**	**Pexp**
	STAGE I				**STAGE I**			
Conscious level	0.57	0.27 , 0.87	72%	36%	1	0.14 , 1	100%	80%
Head control	0.32	0.1 , 0.54	54%	32%	0.17	-0.03 , 0.37	54%	32%
Assessable?	1	0.15 , 1	100%	80%	1	0.14 , 1	100%	80%
Lips closure	0.04	-0.40 , 0.50	68%	67%	0.63	-0.37 , 1	93%	83%
Pharyngeal sensation	1	0.7 , 1	100%	38%	1	0.5, 1	100%	59%
Weak voice	0.53	0.33 , 0.73	68%	32%	0.36	-0.02 , 0.74	67%	47%
Gag reflex	0.80	0.54 , 1	86%	32%	0.36	-0.14 , 0.86	74%	60%
Voluntary cough	0.77	0.56 , 0.98	84%	33%	0.72	0.47 , 0.97	82%	36%
	STAGE II				**STAGE II**			
Water dribbling	0.82	0.26, 1	93%	65%	0.89	0.63, 1	93%	36%
Laryngeal movement	0.88	0.53 , 1	93%	47%	1	0.74 , 1	100%	40%
Repeated laryngeal movement	0.76	0.47 , 1	85%	40%	1	0.19 , 1	100%	76%
Cough stage II	0.29	-0.3 , 0.88	91%	88%	1	0.19 , 1	100%	76%
Choking stage II	0.43	-0.4 , 1	87%	78%	0	---	100%	100%
Voice quality stage II	0.32	0 , 0.64	61%	42%	1	0.19 , 1	100%	76%
	STAGE III				**STAGE III**			
Complete assessment	1	0.5 , 1	100%	59%	1	0.6 , 1	100%	52%
Cough stage III	0.50	0.17 , 0.83	73%	48%	1	0.6 , 1	100%	52%
Choking stage III	0.43	0.10 , 0.76	69%	45%	0.73	0.11 , 1	90%	63%
Voice quality stage III	0.3	-0.08 , 0.68	63%	46%	-.01	-1 , 1	80%	82%
Swallowing safety	0.64	0.4 , 0.88	80%	61%	0.9	0.7 , 1	93%	34%

("Sips" and "Time" were omitted from this Table)

Table A.2 SSA: Interobserver agreement between raters with full training (T), partial training (PT) and non training (NT).

SSA	Raters "T"			Raters "PT"			Raters "NT"		
	K	Pobs	Pexp	K	Pobs	Pexp	K	Pobs	Pexp
STAGE I									
Conscious level	0.63	89%	70%	1	100%	80%	0.63	89%	70%
Head control	0.19	42%	28%	0.37	56%	30%	0.52	67%	31%
Assessable?	1	100%	80%	1	100%	80%	1	100%	80%
Lips closure	0.64	94%	83%	0.0	99%	94%	1	100%	80%
Pharyngeal sensation	1	100%	60%	0	100%	100%	1	100%	38%
Weak voice	0.52	75%	48%	0.32	63%	45%	0.47	63%	30%
Gag reflex	0.75	88%	51%	0.40	75%	59%	0.73	88%	53%
Voluntary cough	0.9	94%	38%	0.71	81%	35%	1	100%	34%
STAGE II									
Water dribbling	0.85	94%	60%	1	100%	50%	1	100%	63%
Laryngeal movement	0.89	94%	43%	1	100%	41%	1	100%	41%
Repeated laryngeal movement	1	100%	65%	1	100%	76%	0.75	88%	50%
Cough stage II	0.66	94%	82%	1	100%	76%	0	88%	88%
Choking stage II	0	93%	93%	1	100%	86%	0.6	88%	69%
Voice quality stage II	0.79	93%	66%	1	100%	74%	0.58	75%	41%
STAGE III									
Complete assessment	1	100%	56%	1	100%	52%	1	100%	59%
Sips*	0	80%	80%	0.2	50%	38%	0	100%	100%
Time**	0	50%	50%	0	100%	100%	0	50%	50%
Cough stage III	0.8	90%	50%	1	100%	52%	0.7	86%	53%
Choking stage III	0.62	90%	74%	0.74	90%	62%	0.72	86%	49%
Voice quality stage III	-0.05	80%	81%	0.0	80%	80%	0.46	71%	47%
Swallowing safety	0.82	88%	34%	1	100%	34%	0.61	75%	36%

* Classified as ≤6 and >6

** Classified as ≤15, 16-30 and >30 seconds

study. All raters observed the same swallowing assessment and this may explain the improved agreement even in the group without prior training. Conferring, however, is possible in a design of this kind. For instance, the raters found it very difficult to assess the pharyngeal sensation, and consequently discussed their findings during the assessments.

The difficulties encountered in the assessment of the pharyngeal sensation in this study contradict the experience of Davies et al [46], who found it to be highly reliable.

Overall, the results of the raters, who had training prior to the use of the SSA, showed a good agreement. Thus the SSA can be used for the screening of dysphagia in acute stroke by different assessors, after a short training period.

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