The Case of Elaine Bromiley

The following 15 pages provide an anonymous version of an Independent Report on the death of Elaine Bromiley. Page 17 is an anonymous copy of the Coroner's Inquest Verdict. The verdict is not a short verdict (i.e. one or two words) but a narrative verdict describing what happened. Page 18 is a summary and a correction to Prof Harmer's timeline based on new evidence which was presented at the Inquest (Prof Harmer was unable to interview the ENT Surgeon as part of his report).

You have the family's permission to copy and use the report and verdict in any format you believe useful for the purpose of learning. Professor Michael Harmer's name is used with his permission.

Martin Bromiley

So that others may learn, and even more may live

Independent Review on the care given to Mrs Elaine Bromiley on 29 March 2005.

Prepared by:

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Professor of Anaesthetics and Intensive Care Medicine,

Introduction

This independent review was commissioned by The xx Clinic in response to the death of Mrs Elaine Bromiley. The review had been requested by the deceased's husband, Mr Martin Bromiley, as a means of ascertaining, as far as possible, the events that lead to Mrs Bromiley's demise.

The terms of reference for this review were agreed as:

- 1. The inquiry should be undertaken by an anaesthetist who is not employed by The xx Clinic or (NHS) Hospital.
- 2. The first objective would be to establish what happened in The xx Clinic on 29 March 2005, but should not overlook any pre- or postoperative factors that may be considered relevant.
- 3. The second objective would be to establish if any lessons can be learned from what had occurred and to disseminate this information across appropriate people in the industry. This should be done whilst retaining the confidentiality as far as possible of the staff involved.
- 4. The inquiry should not under any circumstances attempt to apportion blame.
- 5. The (NHS) Hospital and/or xx Clinic management, press or public should not have access to the inquiry and should not attempt to influence in any way the findings of the inquiry. However, the results should be available to management and interested parties, including relatives.

The Association of Anaesthetists of Great Britain and Ireland was contacted at the end of April 2005 to seek advice regarding a suitable person to undertake this independent review. Given the serious nature of the incident and the particular area of concern, it was decided that the current President, Professor Michael Harmer, was the most appropriate person to undertake the task.

Credentials of Reviewer

I am Professor of Anaesthetics and Intensive Care Medicine at the Wales College of Medicine, Cardiff and have held that post since 1997. Prior to my academic appointment, I spent 13 years working as a Consultant Anaesthetist in the National Health Service with special interest in a range of major surgery. I have worked with an ENT surgeon for more than 20 years and have a wide experience of providing anaesthesia for all types of ENT procedures. My clinical experience in head and neck surgery, and obstetric anaesthesia lead to my interest in managing difficult airways. I have written several papers and chapters on the topic and have lectured around the world on aspects of difficult airway management. I have been a member of the Difficult Airway Society since its inception and have been involved in the development of several courses relating to the subject.

I am currently an elected member of the Council of the Royal College of Anaesthetists and was, until the end of my term in 2004, an examiner for their Final Fellowship. Until 2003, I was Editor-in-Chief of the peer-reviewed journal, Anaesthesia. I am currently President of the Association of Anaesthetists of Great Britain and Ireland (AAGBI).

The Review Process

Following discussions with the management of The xx Clinic, copies of relevant notes and statements of staff involved in the incident were obtained. Following perusal of the information provided, key staff were interviewed individually during a visit to the hospital on 24 May 2005. Prior to the production of this report, it has been possible to speak to all staff involved with the exception of the ENT surgeon, (Mr E) his involvement in events is ascertained from his personal statement and the comments of those interviewed.

The following were personally interviewed and provided written records of events:

- Dr A, Consultant Anaesthetist
- Dr B, Consultant Anaesthetist
- Ms K, Senior Operating Department Practitioner
- Mr G, Operating Department Practitioner
- Ms S, Recovery Nurse
- Ms D, Senior Staff Nurse, Recovery
- Ms C, Theatre Nurse

At all times during this inquiry, the management and staff of The xx Clinic, and the Clinicians involved with event have been open and cooperative.

Outline of Report

This report, based on written and oral evidence, will consider the following aspects pertaining to the events of 29 March 2005:

- a. Facilities and staffing at The xx Clinic
- b. Background information regarding Mrs Bromiley
- c. Outline of medical staff involved
- d. Immediate pre-operative anaesthetic management
- e. Anaesthetic management on 29 March 2005
 - i) Pre-anaesthetic management
 - ii) Anaesthetic technique and management of airway problem
- f. Immediate postoperative care
- g. Subsequent clinical management
- h. Appropriateness of clinical management
- i. Conclusions and suggested actions.

Facilities and staffing at The xx Clinic

The xx Clinic is a modem independent healthcare facility that is situated adjacent to (NHS) Hospital. The facilities available within the operating theatre complex are of a very high standard. In particular the availability of monitoring is at least to the level of that detailed in the AAGBI document on Minimum Standards of Monitoring. Such monitoring is available in both the operating theatre and the anaesthetic room. The overall standard of anaesthetic equipment is high with modem anaesthetic machines and ancillary equipment. In addition to the anaesthetic machines, there is ready availability of a wide range of adjunct equipment.

With particular reference to equipment that might be needed for a difficult airway problem, there was appropriate equipment available including a full range of laryngoscopes, endotracheal tubes, laryngeal mask airways, intubation bougies and a fibreoptic intubating bronchoscope. There was also equipment for percutaneous and surgical access to the airway readily available. The only piece of equipment that that was not available, that might be of value with a difficult airway, is an Aintree Catheter (a disposable long thin tube that can be used as an introducer for an endotracheal tube and allows oxygen to be administered at the same time). The fact that this piece of equipment was not available does not imply that it is viewed as mandatory to be available in every operating theatre, in fact it is my impression that the UK-wide position is similar to that found at The xx Clinic. It is also unlikely that an Aintree Catheter would have been of essential importance in the problems encountered with Mrs Bromiley.

The level of staffing of appropriate grade and skill at The xx Clinic was of a standard above the average one would expect to see. In particular, the support available to the anaesthetist both as a primary assistant and as secondary back-up was both appropriate and above the level that one would find in the average NHS hospital. The availability of additional staff when problems arose is also noteworthy and all involved in the events of 29 March 2005 would appear to have been well prepared and responded appropriately. The quality of recovery room staff was also of a high standard and suitably experienced for the role.

Thus, from my observations, I would conclude that as far as the staff and facilities of The xx Clinic are concerned, there was a high standard of equipment and staff. The level of each was higher than that found in the average NHS hospital. The only piece of equipment that was not present in the operating theatre was an Aintree Catheter — that omission did not, in my opinion, influence the outcome of the problem with the difficult airway.

Background information regarding Mrs Bromiley

Mrs Elaine Bromiley was a 37-year-old mother when she presented at The xx Clinic on 29 March 2005 for surgery to her nose. On the day of surgery, she arrived at the hospital at about 07.30. She had been assessed prior to admission on 21 March 2005. At that time, the pre-operative assessment questionnaire highlighted only one matter of note

— that she had a congenitally fused vertebra in her neck. The only other matter of note was that she was using a nasal spray twice a day to help the nasal symptoms. She had had previous anaesthetics for repair of a hernia and an appendicectomy at age 7 years, and had had two Caesarean sections 4 and 1/2 years ago (there is no mention of the type of anaesthetic used but given modern practice, one would assume that these had been under local anaesthesia).

Given the lack of any significant cardiovascular or respiratory symptoms, and the relatively minor nature of the intended surgery, the only investigation that was requested was a full blood count (FBC) to check the level of haemoglobin. This level of investigation was appropriate in this case.

Mrs Bromiley was admitted under the care of Mr E, ENT surgeon, who clearly saw her when she was admitted and completed the operation consent form with her. The scheduled surgery was endoscopic sinus surgery and septoplasty.

Outline of medical staff involved

The consultant ENT surgeon, Mr E, is an experienced surgeon who has worked for many years both in the NHS and the independent sector.

The consultant anaesthetist, Dr A, is an established consultant working in both the NHS and independent sector. His NHS colleagues comment that he is a very diligent and caring doctor who practices 'careful' anaesthesia.

Dr B, consultant anaesthetist, was working in the adjoining operating theatre on the morning of 29 March 2005 and became involved in the management of Mrs Bromiley as he had additional skills pertaining to the difficult airway. He again is a respected consultant working in both the NHS and independent sectors.

There is nothing to suggest that any of the medical staff involved were not experienced nor up-to-date with their continuing professional development (though this latter fact has not been checked).

Immediate pre-operative anaesthetic management of Mrs Bromiley

It is clear from the clinical notes that Mrs Bromiley was seen by Dr A prior to her operation. The anaesthetic chart notes: 'Previous GAs OK'; 'cervical vertebrae fused congenitally'; 'generally well'; 'medication, nasal drops'; 'allergies, nil known'; 'non smoker'; 'occasional alcohol'; 'no dental problems'; 'starved'. In addition, there is a separate assessment of the airway: 'mouth opening OK'; 'Mallampati'; 'neck movements slightly restricted'.

The proposed plan was for a general anaesthetic for the procedure. In addition, analgesia was discussed and the use of rectally-administered diclofenac (a non-steroidal anti inflammatory painkiller) was covered.

The blood pressure and haemoglobin levels were within the normal range for a woman of Mrs Bromiley's age.

There would not appear to be anything of particular note in the pre-operative anaesthetic assessment and management. The existence of a neck problem was identified and its possible impact predicted by airway assessment. Whilst there was slight restriction in neck movement, there was nothing to suggest that Mrs Bromiley would pose a particular problem with regard to airway management during anaesthesia. This was the impression Dr A had and in his comments he enlarges on his pre-operative findings. With regards to the neck problems, there appeared to be little restriction in flexionlextension (head forward and backwards) with only a little limitation in rotation. Mouth opening was normal, as was the thyro-mental distance. The Mallampati score (a measure of predicted difficulty in tracheal intubation) was grade II. Dr A felt that these findings did not constitute a major difficult airway potential — a view with which I would concur.

The proposed anaesthetic technique as outlined in Dr A's comments was to avoid tracheal intubation and maintain the airway with a laryngeal mask. Anaesthesia was to be maintained with isoflurane (a potent inhaled anaesthetic agent) carried in a mixture of nitrous oxide and oxygen (routine carrier gas mixture). Analgesia would be provided with an infusion of remifentanil (a very potent short-acting analgesic). This was, in my opinion, a reasonable proposed technique.

Anaesthetic management

a) Pre-anaesthetic management

Mrs Bromiley was 'checked in' for surgery by Ms K, senior operating department practitioner and main assistant to Dr A. She noted that there was a history of fused cervical vertebrae and commented upon it. She was assured by Mrs Bromiley that it had not been a problem.

On arrival in the anaesthetic room at about 08.30, routine monitoring was set up. This was a blood pressure cuff (to measure blood pressure regularly during the operation), an ECG (monitor of heart electrical activity) and a pulse oximeter (monitor of the oxygen level in the blood). These are routine monitors that are attached to all patients having a general anaesthetic. This level of monitoring is as recommended in the AAGBI guidelines. An intravenous cannula was placed in Mrs Bromiley's left hand prior to administration of the anaesthetic.

Prior to the induction of anaesthesia, the pulse rate was 81 bpm with an oxygen saturation of 98% (both normal); there is no record of the blood pressure at that time. There is no record of a period of pre-oxygenation prior to induction of anaesthesia (a procedure that allows a store of oxygen to be in the lungs should problems arise).

b) Anaesthetic technique and management of the airway

I have endeavoured to construct a timescale for events during the anaesthetic but there is no information recorded on the anaesthetic chart. The following is based on the other clinical notes and comments for staff:

- **08.35** Anaesthesia was induced with an infusion of remifentanil (0.3mcglkg/min) and an intravenous injection of propofol 200mg (a very rapidly-acting anaesthetic agent). The proposed airway management was with a flexible laryngeal mask airway but it was not possible to insert this due to inability to open the mouth as a consequence of increased tone in the jaw muscles. This can sometimes occur when anaesthesia is 'light' and is usually overcome by giving an additional dose of anaesthetic. In this case, Dr A gave another 50 mg of propofol and had a second attempt. He tried two sizes of laryngeal mask (sizes 3 and 4) but was unable to insert either.
- **08.37** At this stage, Mrs Bromiley's oxygenation began to deteriorate and she looked cyanosed (blue). Her oxygen saturation at this time was 75% (anything less than 90% is significantly low) and her heart rate was raised.
- **08.39** The oxygen saturation continued to deteriorate to a very low level (40%) over the next minute or so. Attempts to ventilate the lungs with 100% oxygen using a facemask and oral airway proved extremely difficult.
- **08.41-08.43** It was still proving near impossible to ventilate the lungs and the oxygen saturation remained perilously low (40% it might have been lower but I think the monitor had a lower limit of 40%). In combination to the extremely low oxygen saturation, the heart rate had declined to 69 bpm with a downward trend continuing to the low 40's. This is indicative of lack of oxygen to the heart.

Dr A decided to attempt tracheal intubation at this stage to overcome the problems with the airway. He gave atropine 0.6 mg intravenously (a drug to counter the slow heart rate) and suxamethonium 100 mg (a paralysing drug to allow insertion of the tracheal tube).

At about this time, Dr A was joined by Dr B who had been about to start an operating list in the adjoining theatre.

08.45 On insertion of the laryngoscope to allow insertion of the tracheal tube, it was impossible to see any of the laryngeal (voicebox) anatomy. This view at laryngoscopy is classified as Connack and Lehane grade IV and means that tracheal intubation is likely to be very difficult if not impossible. The oxygen saturation remained very low though the heart rate had increased to 64 bpm, probably as a result of the atropine.

By about this time, other staff had been summoned to the anaesthetic room to provide any necessary assistance. Mr E also entered the anaesthetic room at about this time. Between attempts at laryngoscopy, ventilation still proved extremely difficult despite the use of four-handed attempts.

The situation now was that termed 'can't intubate, can't ventilate' and is a recognised emergency in anaesthetic practice for which guidelines are available.

08.47-08.50 Further attempts at laryngoscopy and intubation were made using different laryngoscopes by both Dr A and Dr B, but to no avail as the larynx could not be seen. Dr B attempted visualisation with a fibre-optic flexible scope but was unable due to the presence of blood obscuring the view through the scope.

The oxygen saturation remained very low at 40% and the heart rate again was beginning to slow.

By this time, staff had ensured that all possibly-needed equipment including a tracheostomy set was available in the anaesthetic room or in the close vicinity.

08.51-08.55 Mr E attempted intubation with a standard anaesthetic laryngoscope. He was able to see the very end of the epiglottis (top part of the larynx) and attempted to pass a bougie into the larynx over which a tracheal tube could be 'railroaded'. He was unsuccessful.

The oxygen saturation remained low at 40%. There was a recordable blood pressure and the heart rate was now high at 140 bpm.

08.55 Insertion of an intubating laryngeal mask allowed some ventilation, though it still remained difficult to ventilate the lungs. At the time of insertion of the intubating laryngeal mask, the oxygen saturation was still low at 40% and the pulse rate was high at 133 bpm.

09.00 The insertion of the intubating laryngeal mask improved matters and the oxygen saturation rose to 90% with a raised blood pressure and heart rate. At this time, a dose of steroids (dexamethasone 8 mg) was given, presumably to help protect the brain from hypoxic damage.

09.03-09.09 Attempts were made to insert a tracheal tube through the intubating laryngeal mask. Initially, the attempt was undertaken blindly (as the device is intended to work) and then using a fibre-optic flexible scope. The latter attempt by Mr E failed as he was unable to pass the scope through the end of the laryngeal mask (a recognised problem with this device).

During these attempts, the oxygen saturation was unstable, dipping down to 49% on occasion. At no time did it exceed 90%.

09.10 In view of the problems encountered, it was decided to abandon the procedure and allow Mrs Bromiley to wake up.

09.13-09.29 During this time, the remifentanil infusion was stopped and spontaneous breathing began (up till that time, the lungs had been ventilated by squeezing the bag on the anaesthetic machine). The laryngeal mask was removed and an oral airway inserted. Oxygen saturations gradually improved reaching near normal levels of 95%. Throughout this time, the blood pressure was markedly elevated (as high as 192/126 mmflg) and the heart rate was also very high (up to 152 bpm).

Once Dr A was happy that Mrs Bromiley was breathing satisfactorily with the oral airway in place, she was transferred to the recovery room. At this time, Dr A thought that Mrs Bromiley was showing signs of recovery and was breathing with a normal pattern.

In total, during the attempts at intubation, Mrs Bromiley's oxygen saturation was extremely low (at or less than 40%) for some 20 minutes.

Immediate postoperative care

Mrs Bromiley was admitted to the recovery room at 09.30. Her observations on admission were a pulse rate of 120 bpm, a respiratory rate of 20 bpm, blood pressure of 84/33 mmHg, temperature of 35.1 °C and an oxygen saturation of 95%. The recovery staff were aware of the problems that had occurred and were informed by Dr A that he would expect Mrs Bromiley to recover consciousness slowly. After a short while with Mrs Bromiley, Dr A left the recovery room to continue the operating list.

It is clear from the statements of the recovery staff (Nurses D and S) and subsequent interviews that they were far from happy with Mrs Bromiley's condition. Even nearly one hour after admission, there was no sign of recovery of consciousness and whilst Mrs Bromiley was breathing, the pattern was erratic. The blood pressure was equally erratic with swings from very high to low; the oxygen saturation equally showed swings. Most concerning to the recovery staff were periodic episodes of movement that looked like 'fits'. These were associated with further swings in measured parameters. Such are signs of cerebral irritation and require prompt, appropriate action.

On several occasions, the recovery staff asked Dr A to come to see Mrs Bromiley but that was not always possible as he had already started to anaesthetise the next patient on the operating list. On occasion, Dr B came to see the patient, but he, quite legitimately, had a duty of care to his own patients. The exact times when requests were made of Dr A are not recorded but it is clear that the recovery staff felt that Dr A should have been readily available to deal with any problems.

Concerns increased and eventually it was decided that Mrs Bromiley needed to be transferred to the intensive care unit. As both Dr A and Dr B were unavailable, (another Anaethetist) attended to supervise the transfer. This took place at about 11.00 and Mrs Bromiley was transferred to (NHS) Hospital. At this time, she was in an unstable condition though was still breathing on her own.

The exact sequence of events is not entirely clear as there is no record of measurements made. It is normal practice to have written records of cardiovascular variables and I can only assume that if such exists, that it has been mislaid.

Subsequent management

It was not within the brief of this inquiry to consider the management of Mrs Bromiley outside The xx Clinic and hence this section reflects an overview of the situation.

On admission to the intensive care unit at (NHS) Hospital, it was clear that Mrs Bromiley had suffered marked brain damage and urgently required ventilation. Again there were problems with placing a tracheal tube, finally it was possible to insert one through her nose and into her trachea.

Mrs Bromiley's condition did not improve and her clinical course lead to her ultimate death. There was clear evidence of severe cerebral damage through her time on the intensive care unit.

Appropriateness of clinical management

There are a number of areas where the clinical management of Mrs Bromiley fell short of what one might reasonably expect. It is impossible to say what would have happened if her management had been different, as this was an unusual case as there was little to suggest the extent of the problem that was encountered.

In order to provide some structure to this section, I shall tackle the areas in a chronological order pointing out where I believe management was acceptable and where there was, in my opinion, inappropriate management.

Facilities and staff at The xx Clinic

There was nothing lacking in the staffing and facilities at The xx Clinic. The one piece of equipment that was not available on the day of the incident is not essential and would not be present in every hospital. The standard of care given by the staff was, in my opinion, exemplary.

Pre-operative assessment and preparation

The pre-operative assessment that took place on 21 March 2005 was entirely adequate and investigations were appropriate.

The pre-operative assessment made by Dr A on the day of surgery was equally appropriate and adequate. He had identified and, to the best of his abilities, quantified the potential risk associated with the neck stiffliess. The bedside tests he undertook were entirely appropriate and represent good practice. His opinion was that whilst there was a potential problem, it did not represent a major hazard — an opinion with which I would agree.

Thus, I do not feel that there was anything in the pre-operative assessment and management that was anything but good and appropriate practice.

Anaesthetic technique

The choice of a general anaesthetic for this procedure was appropriate and the drugs used were those with which Dr A was familiar. There are many options for which agents one might use for such an operation, and those chosen are quite appropriate.

It is some anaesthetists' practice to routinely give the patient 100% oxygen to breath for a few minutes prior to induction of anaesthesia. This allows the washing out of nitrogen from the lungs and its replacement with oxygen that provides a store should problems arise in the early part of the anaesthetic. It is my practice to routinely do this but many anaesthetists do not unless there is a specific indication. There was no specific indication in this case and it probably is a reflection of Dr A's normal practice. I do not consider pre-oxygenation to be mandatory in a case such as this.

Intended airway management

The intended method of airway management for the procedure (use of a laryngeal mask airway) was particularly appropriate as not only did it allow good surgical access, it eliminated the need for tracheal intubation, If the neck problem was to present a problem, it would be in tracheal intubation; by avoiding intubation, theoretically any problem would be avoided.

When it was impossible to insert the laryngeal mask airway, it was assumed that it was as a result of muscle tone caused by light anaesthesia. This is entirely reasonable and is a not uncommon problem. An additional small dose of anaesthetic is usually enough to allow insertion. I would agree with this course of action.

When it was not possible to insert the laryngeal mask or to inflate the lungs with a 'bag and mask', it is necessary to take appropriate actions. In the hands of an experienced anaesthetist such as Dr A, the most appropriate action at this stage is tracheal intubation. He administered the muscle relaxant, suxamethonium, and quite reasonably would have expected to be able to see the larynx and place a tracheal tube. When this was not possible, he was confronted with one of the most feared anaesthetic situations of a patient who you cannot intubate or ventilate who is hypoxic (lack of oxygen).

I believe that Dr A's actions up to this point are appropriate and in keeping with acceptable practice.

Management of 'Can 't intubate, can't ventilate'

This situation is an emergency and requires rapid and appropriate action if it is not to end in disaster. Over the years there have been many 'failed intubation drills' published with different lines of action. In recent years, the Difficult Airway Society (DAS) has produced guidelines for exactly this eventuality (copy attached at end of report). They are based on the one underlying important measure — to ensure the return of adequate oxygenation as soon as possible. The guidelines are intended primarily for the situation where intubation is the first airway management technique used and so are not entirely appropriate in this case. The guidelines for unexpected difficult intubation consist of plans A, B, C and D. As can be see, they are fairly easy to follow and have been widely publicised in the journals recently.

I would have expected Dr A to follow the guidelines in ensuring adequate oxygenation as the first priority in this case rather than persistent attempts at intubation. The DAS guidelines suggest an intubating laryngeal mask as the Plan B when intubation has failed. Although this was the method eventually used by Dr A, more than 20 minutes had passed since Mrs Bromiley first became hypoxic. It is a well-known fact that persistent attempts at intubation when one is unable to ventilate the lungs between attempts is a very serious matter and often has an untoward outcome with hypoxic brain damage. For that reason, when in a situation of 'can't intubate, can't ventilate', early recourse to providing an alternative route to the airway is advocated either by surgical or percutaneous cricothyrotomy.

These are well recognised techniques that all anaesthetists should be familiar with and be able to perform. In this case, both the equipment and appropriate staff were available to perform the procedure; the presence of an ENT surgeon is an added bonus in this situation and he would have been able to undertake the surgical procedure, if Dr A had been unable to perform a percutaneous technique.

It is hard to understand why Dr A, and those with him, persevered in trying to intubate the trachea when standard teaching would be to ensure oxygenation within three minutes of the start of severe hypoxia. It is particularly difficult to understand when an experienced ENT surgeon was actually in the room. To attempt intubation by the many methods caused further delay in a definitive solution. However, when in such an emergency situation, it is surprising how quickly time goes by and whilst concentrating on solving the intubation problem, I suspect that Dr A was not aware of how much time had passed. In my interview with him, he said he had no idea that some much time had passed and had he been aware of the passage of time, he would have resorted to a surgical access to the airway. He still does not know why he did not do so. The problem of the passage of time is well known and yet such information is seldom provided in situations such as this; some form of regular prompting would be very helpful.

Thus, I believe that the management of the 'can't intubate, can't ventilate' situation left something to be desired and certainly did not follow the current guidance in this matter. Even if the guidelines had been followed, there is no guarantee that the outcome would have been different but patients have survived similar unexpected events where emergency airway access has been provided.

Further attempts at intubation through the intubating laryngeal mask

Whilst one can understand the desire to secure the airway with a tracheal tube, it was debatable why, when oxygenation was improving, further attempts were made to perform

this task with deleterious effects. It is recognised that blind intubation through the intubating laryngeal mask is not always successful, even though the apparatus is designed to be used this way. For that reason, most anaesthetists experienced in this area will use a fibre-optic scope to place the tube through the laryngeal mask. At the end of the intubating laryngeal mask is a flap that has to be negotiated; contrary to Mr E's assertion that this is normally cut off before use in this situation, it is negotiated by first pushing a tracheal tube through before passing the scope. It is of some concern that both Mr E and both anaesthetists seemed unaware of this well-known fact and further begs the question as to whether further attempts at intubation should have been undertaken if the operator is not familiar with the equipment. The need for intubation at this time in this setting is particularly pertinent as the DAS guidelines would suggest that if the surgical procedure is elective and ventilation and oxygenation has been achieved, there should be no consideration of continuing with the case but one should immediately awaken the patient.

Decision to awaken the patient

As already implied above, in an elective situation where there has been problems in ventilation which have been overcome, there is really no indication for keeping the patient anaesthetised and they should be allowed to regain spontaneous breathing and wake up. This will allow consideration of the problem and development of an alternate strategy for the future.

However, in a situation such as with Mrs Bromiley where there has been an extensive period of gross hypoxia (up to 20 minutes) it is almost inevitable that there will be at least some cerebral irritation or frank damage. Such damage can be minimised by ensuring that there is continuing adequate oxygenation and ventilation. The development of inadequate ventilation leads to a reduced oxygen and increased carbon dioxide level, both of which are detrimental to the brain in its damaged condition. After such a prolonged hypoxic period, it would be best to provide a period of controlled ventilation and brain monitoring rather than attempting to wake up the patient and leaving them with potentially reduced ventilation.

To follow this line would require tracheal intubation which is already known to be difficult, if not impossible. In my opinion, this was another time when surgical airway access should have been considered as it would not only have provided a secure airway but also have allowed optimal postoperative ventilatory care.

Transfer to recovery

Given the prolonged period of hypoxia, I believe that Mrs Bromiley should have been admitted to an intensive care unit. She should have had a secure airway inserted and her lungs ventilated. In addition she should have had invasive monitoring instituted to allow optimal management of blood pressure. All the expertise and equipment to undertake this was available in the operating theatre at The xx Clinic. To send her to recovery in an unconscious state and breathing spontaneously was inappropriate and would not have helped any existing cerebral damage.

Handover of care in recovery

Given her poor state on admission to recovery, I am surprised that the nurses accepted the transfer of care of Mrs Bromiley from Dr A. Although in everyday practice, this formal transfer of responsibility is 'a taken', in such a situation, I would expect a specific and detailed discussion and formal handover of care. During my interviews with the recovery nurses, it was clear that no such process occurred. In defence of Dr A, if there was no formal transfer process in everyday practice, he may have assumed that the nurses were happy.

If there had been no proper transfer of care from Dr A to the recovery nurses, it was entirely inappropriate for him to go back to theatre and start another operation; he has a continuing duty of care to his patients that has not been discharged. Even if there had been a transfer of care, in such a case, I would expect the anaesthetist to stay with the patient until they had recovered and to find someone else to anaesthetise the rest of the operating list. The situation with Mrs Bromiley was far from satisfactory as the recovery nurses were not given the appropriate support from Dr A and they became increasingly concerned about her condition. From the statements of the recovery nurses and both anaesthetists, it is clear that there were obvious signs of cerebral irritation that needed intensive care.

Care in recovery

Given her condition and the inappropriateness of her transfer to recovery, I believe that the recovery staff provided good care to Mrs Bromiley. They were clearly concerned about her condition but did not seem to have the degree of support that they might expect from Dr A. If there is a criticism, it relates to the lack of written recording for the period of stay in recovery. Having spoken to the staff involved, I believe that the record must have been mislaid.

Transfer to intensive care unit

As I have already stated, in my opinion, Mrs Bromiley should not have been admitted to recovery but gone directly to intensive care, but only after a patent airway had been secured. In the event, when it was decided to transfer Mrs Bromiley, it was done without a secured airway. When she arrived at (NHS) Hospital, there were again problems with intubation and only after several attempts was it possible to pass a tracheal tube and secure the airway.

It would have been more appropriate, in my opinion, for Mrs Bromiley to have had her airway secured before transfer. Those already in the theatres were aware of the problems and would have thought out how to get around the difficulties, or they could have summoned appropriate skilled assistance from other colleagues elsewhere to come to The xx Clinic where all the necessary staff and equipment were available. Transferring such an unstable patient without a secure airway was an unnecessary risk.

Management in (NHS) General Hospital

As I alluded to earlier, this is an area of care outside the terms of reference for the inquiry but I believe, Mrs Bromiley received the best possible care but unfortunately the damage to her brain caused by the prolonged period of hypoxia was so extensive that recovery was unlikely.

Conclusions and suggested actions

As is clear from the report, I believe that Mrs Bromiley suffered severe cerebral damage as a result of her extended period of hypoxia subsequent upon the unexpected difficulty in maintaining her airway during anaesthesia.

The staff and facilities at The xx Clinic are of a high standard. There is a good level of equipment in the hospital to deal with difficult airways. The only piece of equipment not available at the time of my visit in May was an Aintree Catheter. It would be prudent to provide this piece of equipment.

Suggested action: Purchase of Aintree Catheter for use in difficult intubation

The pre-operative assessment and anaesthetic management was of an appropriate standard as was the choice of anaesthetic technique and drugs.

The initial airway management was appropriate and in keeping with acceptable practice.

The management of the 'can't intubate, can't ventilate' situation did not follow the accepted Difficult Airway Society guidelines. In particular too much time was taken in trying to intubate the trachea rather than concentrating on ensuring adequate oxygenation by other means such as direct access to the trachea. Whilst theatre staff ensured that all necessary equipment was available, the clinicians appeared to become oblivious to the passing of time and thus lost opportunities to limit the extent of damage caused by the prolonged period of hypoxia. Given the skill mix of the clinicians, it would have been very easy to perform a surgical procedure to gain access to the trachea. Theatre staff, when interviewed, all seemed surprised that such was not performed. Suggested action: Ensure an atmosphere of good communication in the operating theatre such that any member of staff feels comfortable to make suggestions on treatment.

The Difficult Airway Society guidelines are fairly new (2004) and it may be useful to have copies of them on display in the anaesthetic rooms to act as a prompt should such an event occur again.

Suggested action: Obtain and display a set of the latest DAS guidelines in each anaesthetic room

Given the problem with time passing unnoticed, should such an event occur again, a member of staff should be allocated to record timings of events and keep all involved aware of the elapsed time.

Suggested action: Develop a protocol to ensure that when any emergency event occurs, be it in the anaesthetic room or the operating theatre, there is someone designated to keep full contemporaneous records of the event and to provide an elapsed time prompt. It was clear that clinicians were not entirely familiar with some of the particular peculiarities of some of the equipment used. This might be rectified by a study day on difficult airway management for all staff including clinicians.

Suggested action: Organisation of a study day on airway management with particular reference to equipment not regularly used and any particular peculiarities.

There was no written record of events during the anaesthetic. A full chart should always be written whatever the situation. This is the responsibility of the anaesthetist but could be reinforced by recovery staff not accepting the care of a patient without a completed chart.

Suggested action: Ensure that all patients have a completed anaesthetic record before transfer to the recovery area.

There was no clear transfer of care in this case between Dr A and the recovery staff. A more robust, formal handover would make it much clearer to all who is responsible for the patient. Unless the recovery staff are happy to accept the care of the patient, the anaesthetist should not commit to the care of another patient.

Suggested action: The process of transfer of care from the anaesthetist to the recovery staff should be made more formal so there is no confusion over who carries the responsibility for the care of the patient. Under no circumstance must a clinician commit to the care of another patient until care of the previous patient has been transferred and that act is acknowledged.

After a major incident such as occurred here, it is inappropriate for the staff involved, including the clinicians, to continue working immediately. All personnel need time to reflect and ensure that all documentation is completed. Ideally another team should continue the operating list, but as a minimum there should be a break. Suggested action: Any staff involved in a major incident should have an enforced break before continuing with an operating list.

Final Comment

This was a tragic case from which many lessons can and need to be learnt. There were certainly areas where, in my opinion, the clinical practice fell below an acceptable level, but even if the management had been different, there is no way of knowing with certainty that the outcome would have been different.

Professor Michael Harmer MD, FRCA 20 July 2005

This report has been made available by the Bromiley family for the purpose of learning. If you have any questions about this report please contact Martin Bromiley on 07980 301212 or e-mail info@chfg.org

Mrs Elaine Bromiley presented at the xx Clinic, xxxxx on 29 March 2005 for elective surgery for septoplasty and functional endoscopic sinus surgery. There was slight restriction to her neck movement but nothing to suggest a problem with airway management. On arrival in the anaesthetic room routine monitoring was set up, she was not pre-oxygenated. It proved impossible to insert a flexible laryngeal mask and Mrs. Bromiley's oxygenation level began to deteriorate and she appeared blue. Oxygen saturation deteriorated to a low level of 40% and it proved impossible to ventilate her.

A recognised emergency "can't intubate, can't ventilate" arose and there were further failed attempts at intubation. A tracheostomy set was called for but was not used. Oxygen saturation levels remained unstable and at 9.10 the proposed surgical procedure was abandoned to allow Mrs. Bromiley to wake up.

The management of the "can't intubate can't ventilate" emergency did not follow the current or any recognised guidance. Too much time was taken trying to intubate the trachea rather than concentrating on ensuring adequate oxygenation. The clinicians became oblivious to the passing of time and thus lost opportunities to limit the extent of damage caused by the prolonged period of hypoxia. Not all the clinicians were aware that there was a problem with ventilating Mrs. Bromiley.

Surgical airway access by either tracheotomy or cricothyrotomy should have been considered and carried out.

Given the prolonged period of hypoxia Mrs Bromiley should have been admitted to an intensive care unit rather than to the recovery room.

To send her to recovery in an unconscious state and breathing spontaneously was inappropriate. Subsequently transferring Mrs. Bromiley to (NHS) Hospital without a secure airway was an unnecessary risk.

On 5 April 2005 following discussions with the family and assessment by senior clinicians a decision was made to withdraw life support treatment and she died on 11 April 2005.

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<u>Corrected timeline based on Prof Harmer's Report and the Inquest written & verbal evidence.</u>

Anaesthetist and assistant present, thorough pre-op, no pre-oxygenation

0835 Laryngeal mask, GA given, masks didn't fit

0837 Cyanosed, O2 75%

0839 O2 40%

Starting attempts at Intubation

~0841-0843 Heart rate falling, O2 40%, joined by ENT Surgeon, other Anaesthetist and at least 3 Nurses, the team of Consultants tried to intubate. One Nurse went out phone CCU as she was shocked at Elaine's vital signs and colour. On return she announced that "a bed was available in intensive Care", but the Consultants looked at her as if to say "what's wrong, you're over-reacting". She went back to the phone and cancelled the bed. Another asked her colleague to fetch the Trachy kit. On her return she announced to the consultants that "the tracheostomy set is available" but she was ignored.

0845 With hindsight now "can't intubate can't ventilate". Consultants continued to attempt intubation.

0900 eventually got some air to Elaine and 90% oxygenation achieved after over 20 mins at 40%

0910 Consultants appear to decide to let Elaine wake up naturally , transfer to recovery where remained.

Summary produced by Martin Bromiley