

Ref: CGK/SM/Strain report – Belfast 050706

**MEDICO-LEGAL REPORT - ADAM STRAIN (deceased)**

**MR GEOFF KOFFMAN – 5.7.06**

- 1.1 My qualifications are MB, ChB, FRCS. I am consultant surgeon with special interest in paediatric renal transplantation and I am surgical Head of the Paediatric Unit at Guy's & St Thomas Hospital and Great Ormond Street Hospital, London. I am Head of the South Thames Transplant Unit at Guy's & St Thomas Hospital Trust and I have also served as General Secretary and on Council of the British Transplantation Society. I have been a consultant surgeon for 20 years and have personally carried out approximately 500 renal transplants in children during that period of time.
- 1.2 At the request of the Police Service of Northern Ireland I examined copies of case notes of Adam Strain relating to his renal transplant operation in November 1995. I have also examined the reports of all the other medical specialists involved in the management of this case.

1.3 In this report I will review the chronology of the case. I will then proceed to answer specific questions put to me by the Northern Ireland Police and in the final section I will summarise my views on the surgical management of this tragic case. It is important to bear in mind that I have been asked to largely confine my opinion to the surgical management of this case and I will attempt to do this although it is not always possible to separate medical, surgical and anaesthetic management of the patient, particularly in a complex procedure such as a renal transplant.

## 2. CHRONOLOGY

- 2.1 Adam was born 4.8.91 with urethral valves and in addition suffered with vesico-ureteric reflux and repeated urinary tract infections. Despite anti reflux surgery he developed end stage renal failure and commenced peritoneal dialysis in September 1994.
- 2.2 Adam required feeding via a gastrostomy tube as he had virtually no appetite and he had also undergone a fundoplication for oesophageal reflux in March 1992. He underwent an orchidopexy and change of gastrostomy tube in October 1995, just prior to his admission for the renal transplant.
- 2.3 Apart from renal failure he was a healthy well nourished boy with a good urine output. He was fed using the gastrostomy route with approximately 600 mls of Nutrizon during the day and 1500 mls at night. He was on 50th centile for height and 95<sup>th</sup> for weight. He had suffered no ill effects from previous operative procedures all performed under general anaesthetic.

- 2.4 He was placed on call for renal transplant in 1994 and received an offer of a kidney from a 16 year old donor through UK Transplant. The donor kidney had been removed from a heart beating donor who had normal renal function at 1.42am on the morning of 26<sup>th</sup> November. By the time the kidney was implanted into Adam and perfused with blood the total storage time was approximately 34 hours. This is considerable longer than the average storage time which is approximately 20 hours.
- 2.5 At 11pm on 26<sup>th</sup> November his serum sodium was 139 and Hb 10.5. He was given 900 mls Dioralyte which is a dilute solution of saline mixed with 4% dextrose via the gastrostomy in order to maintain his state of hydration. There is a clear entry in the notes stating that the electrolytes were satisfactory but should be repeated first thing in the morning because he was on Dioralyte over night rather than his normal Nutrizon. In the event repeat electrolytes analysis was not performed prior to surgery. There is also no clear indication of the amount of urine that Adam passed but it seems to be commonly agreed that he was polyuric and could cope with an oral intake in excess of 2 litres a day.
- 2.6 The transplant commenced at 7am and was performed by Mr Keane a urological surgeon and Mr Brown a paediatric surgeon. Anaesthetist was Dr Taylor. Adam weighed approximately 21 kgs at this time. At the start of the anaesthetic there was difficulty experienced in inserting a central line because of previous instrumentation to the left sided neck veins and finally a right sided neck line was inserted. It is clear from the x-ray post operatively that the catheter was mal



placed and probably did not give accurate readings of central pressure during the operation. Adam was administered a large volume of 5<sup>th</sup> the normal saline and the first sodium analysis at 9.30am showed severe hyponatraemia with a level of 123 mmol/l (normal range 135 – 145). He also had a very low haematocrit of 18% (normal 35 – 40%). The anaesthetist responded to the low haematocrit and blood was given as well as plasma. There was no response to the low sodium and this fell further to 119 after the end of the operation.

- 2.7 The surgery itself was difficult due to previous operations. The approach was via the loin to the iliac vessels which were mobilised. The renal vein was anastomosed to the external iliac vein and the two renal arteries on a common patch were anastomosed to the iliac artery. The kidney was originally described as perfusing well and a small amount of urine was passed. However the kidney then became discoloured and perfusion was sub-optimal. This would have been a cause for concern by the surgeons and anaesthetists and discussions would have taken place about whether the patient needed further intravenous filling and if so which fluid to use. There was considerable blood loss during the operation (in excess of 1 litre) and this was adequately replaced with two units of packed cells and human plasma protein fraction. The ureter was implanted into the bladder in the conventional way and a suprapubic catheter was put in place.
- 2.8 There was no record of urine output monitored during the procedure. This is not commonly measured during renal transplant surgery because the bladder catheter is usually kept clamped until the ureter to bladder anastomosis is performed.

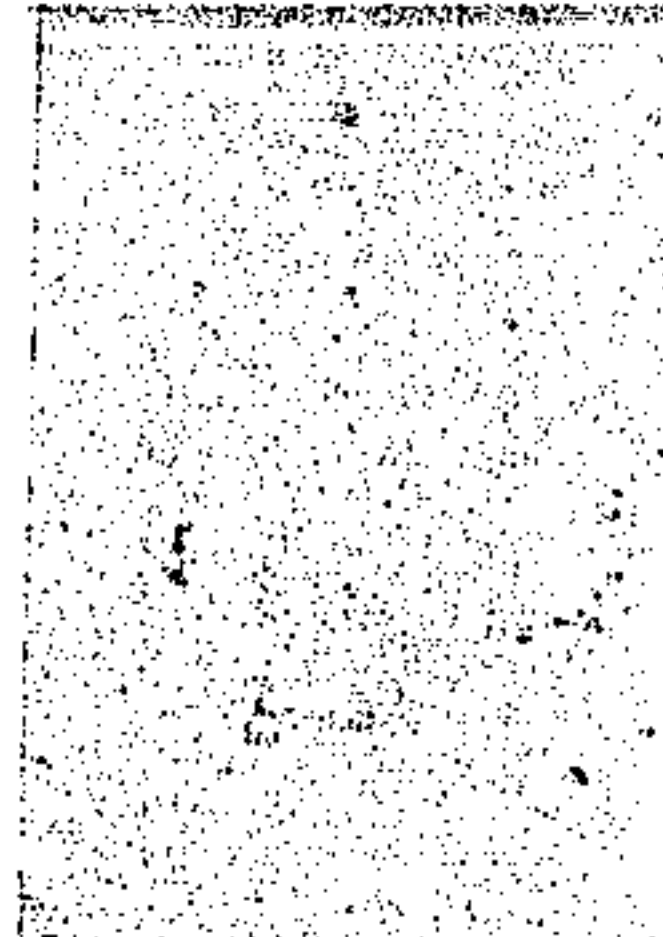
2.9 At the end of the procedure Adam showed all signs of severe cerebral oedema with widely dilated pupils and it is very likely that he was brain stem dead at this stage. He was transferred to the paediatric ITU and cerebral oedema confirmed on CT scanning. There is no evidence that the new transplant showed any sign of function during the few hours between transplantation and patients' death. There is no record of urine output in the post operative period.

2.10 Subsequent post mortem analysis showed an infarcted transplant and there was speculation as to whether the organ was viable prior to transplantation or suffered an injury during or soon after the transplant operation.

### **3. RESPONSE TO SPECIFIC QUESTIONS**

3.1 I am satisfied that Adam was fit to undergo renal transplantation and this was the most appropriate form of treatment for his chronic renal failure. I cannot find a copy of the consent form for the operation. It appears from the records that consent for the operation was not performed by the surgeons but probably by the paediatric nephrologist Dr Savage and this would be normal acceptable practice for the mid 1990s. It would be important to view the consent form and if possible review the topics that were discussed with Adam's mother including the risk of death and serious adverse events from the procedure.



- 
- 3.2 Adam had normal serum sodium and potassium at 11pm the night before surgery. Subsequent to that he had 8 cycles of peritoneal dialysis in order to lower his creatinine and urea and he had an intragastric feed 900 mls of 5<sup>th</sup> normal saline with dextrose. The sodium and potassium should have been repeated prior to start of surgery. The polyuric patient with poor renal function would pass large quantities of dilute urine and may have difficulty controlling the concentration of sodium and potassium in the blood. The importance of this measurement would not have been obvious to the medical teams looking after Adam at the time.
- 3.3 I am satisfied that the preparation by Dr Keane and Dr Brown was in-line with professional standards and despite their lack of experience in paediatric transplantation I would assume that at least one of the surgeons had experience in adult renal transplantation. The principle of the surgery is the same for both children and adults and the major decision would have been about whether to anastomose the transplant renal vessels (artery and vein) to the iliac vessels as in adults or because of Adam's small size to choose larger blood vessels such as the aorta and vena cava for these anastomoses which would entail a different approach. In the event they chose to use the iliac vessels and although this is not the approach I would use normally for a 4 year old, 20 kg child, it is used by some surgeons carrying out paediatric transplants. Therefore I would not criticise the use of this approach.
- 3.4 The two surgeons worked as a team during the surgical procedure and the lead surgeon carries the major responsibility for decision making throughout the operation. The assistant may help with technical aspects of the operation as well

as in decision-making. I could see no report on the record from Dr Brown and such a report would be helpful to confirm Dr Keane's findings.

3.5 The surgeons and the anaesthetists work as a team during the procedure. This is vitally important as the correct level of venous filling and blood pressure are required in order to provide the newly transplanted kidney with adequate blood supply. The surgeons will frequently ask the anaesthetist to provide extra fluid input in order to optimise the perfusion in the transplant kidney. In addition there is dialogue between the two teams in response to excessive blood loss, administration of drugs such as Dopamine and antibiotics. It is not usually the role of the surgeon to decide on the nature of the intravenous fluid replacement and this is virtually always left to the anaesthetist. Where the surgeons have a role is in the decision about whether to replace blood loss with a blood transfusion or to use alternative fluids such as plasma expanders or crystalloid. The surgeons should be aware of BP, CVP measurement and any other blood tests performed during the operation and may ask the anaesthetist to modify the fluid regime accordingly. It is not clear in this case whether the surgeons were aware of the low sodium at 9.30 during the procedure. The consultant anaesthetist Dr Taylor makes no comment in his report about the low sodium during the operation and it seems to me therefore that he did not appreciate the hazard of such a low sodium and also that he probably did not pass this on to the surgeons who were in the middle of a difficult surgical procedure.

3.6 It seems clear that all clinicians involved in the case were satisfied that Adam was fit for transplantation and despite lack of repeated electrolyte results just prior to surgery they would have been reassured by the normal results 8 hours earlier. The usual reason for repeating electrolytes is to ensure that the serum potassium is



not dangerously high and this would have been extremely unlikely with the degree of dialysis that Adam had undergone during the night. There is a possibility that serum sodium would have been low prior to transplantation and ideally electrolytes should have been re-checked. I do not think that it is negligent by the surgeons not to have insisted on this repeat electrolyte result.

- 3.7 There were considerable difficulties experienced during this operation chiefly because of the previous surgery but also partly because of Adam's age and weight. It is impossible to ascertain from the operation note whether the anastomoses were performed in a technically sound way. The kidney appeared to perfuse well initially and passed some urine but then appeared to be less well perfused. There is no record in the operation note of further exploration of the anastomosis or any analysis on whether this was an arterial or venous problem. The other possibility is that it was due to a low perfusion pressure or a severely injured kidney due to donor or storage factors. It is not uncommon for kidneys to behave in this way with an initial good perfusion followed by a period of apparent ischaemia. This usually means a kidney has suffered acute tubular necrosis, reversible process commonly associated with prolonged cold storage times. In this particular case with a storage time in excess of 30 hours acute tubular necrosis and delayed graft function would be expected. It does appear that the surgeons entered into a dialogue with the anaesthetist to try to optimise perfusion of the kidney by blood and plasma transfusion. The failure of a transplant due to venous or arterial thrombosis is a relatively common cause of organ failure. Even in experienced hands there is an incidence of about 2 to 4% and the incidence would be higher with a young recipient. There is no evidence that the operation was performed in a negligent way.



- 3.8 Urine output is not normally recorded during the transplant procedure. The majority of patients undergoing transplantation do not pass a great deal of urine and usually a bladder catheter is clamped in order to distend the bladder to facilitate the ureter to bladder anastomosis. A minority of patients are polyuric and the bladder may be left on free drainage in these patients. It would not be particularly important to monitor the urine output in these patients as the critical monitoring would be central venous pressure and BP which would be achieved by variation in the intravenous fluid administered to the patient. The urine output following implantation of the new kidney and anastomosis of the ureter to the bladder becomes important immediately after the transplant and the surgeon would normally start to record urine output on an hourly basis towards the end of the operation.
- 3.9 Conventionally the surgeon would record the time that the donor kidney was removed from the donor and perfused with cold preservation fluid. He would also record the time that the kidney was removed from ice and the approximate time to perform the anastomosis. We know the first of these parameters but the exact time of removal from ice and the time taken for the anastomosis is not recorded. This is not a critical omission. The kidney is kept cool during the anastomosis and anastomosis times may vary from approximately 20 minutes to 60 minutes in the case of a difficult anastomosis. There is no evidence that the anastomosis time in this case was outside the norm. The surgeon could still provide this information.
- 3.10 The question about the experience of the two surgeons undertaking the operation is difficult. It is not clear how much transplant experience the surgeons had before undertaking this procedure. Of course only the lead surgeon would be

required to have previous transplant experience. It would be unusual for an inexperienced transplant surgeon to undertake a transplant in a child as young as 4 years of age but I would be happy to accept that an experienced urological surgeon who has performed many adult renal transplants should be able to perform a paediatric transplant in a child of this age. Without knowing more detail about Dr Keane's surgical experience, I therefore cannot answer this question fully. I would be grateful if more information could be provided to me in terms of this experience.

- 3.11 An operative time of approximately 4 hours is not unusual in a difficult paediatric transplant and the outcome of surgery is not related to the length of time taken. I would normally expect the anaesthetic time prior to transplantation of a child of this age to be approximately 1 hour, the incision and mobilisation of the blood vessels to take an hour, the anastomosis of the renal artery and vein and subsequent repair of any bleeding vessels to take approximately 45 minutes and the anastomosis of ureter to bladder to take approximately 30 minutes. The time to check for the perfusion, to stop any further bleeding and to close the abdomen would then take another 30 minutes.
- 3.12 The operative record concerning the perfusion of the kidney is rather scanty. However this is not uncommon in operation notes. It is quite common for the kidney to behave like this and initially to perfuse well and then become rather blue and floppy. Many kidneys do not produce urine immediately and some may only produce small amounts of urine in the first hour. I could not see a statement from Dr Brown that the kidney did not pass urine, although I did see that Dr Keane stated that the small amount of urine was produced initially. If there is a statement from Dr Brown I would like to see it.



3.13 The pathologist, Professor Berry states quite clearly that the transplant kidney was infarcted. He also states that the extent of the change suggests that this occurred at or before the time of transplantation. It is clear that the donor kidney was viable at the time it was removed as the donor passed 200 mls of urine in the hour prior to donation. The likelihood is that the kidney was viable at the time of implantation into Adam but there was a subsequent thrombosis of the artery or the vein either due to technical factors or due to low blood flow secondary to acute tubular necrosis or due to some hypercoagulable state. We do not have any further information from the post mortem about the aetiology of the kidney infarction.

3.14 I have commented about the team work between anaesthetist and surgeon and this is particularly important in respect of achieving good central venous pressure and BP levels in order to perfuse the newly transplanted kidney. The balance has to be drawn between excessive venous filling which would be dangerous to the recipient and under filling which would be dangerous to the transplanted organ. In a difficult operation it is vital that the surgeon concentrates on performing the vascular and other anastomosis to his best ability. During this time he would expect the anaesthetist to be providing a healthy physiological background for the transplant and to be informed if there were any unexpected events. The discussion would continue in terms of replacement of blood loss and perfusion pressure at the time of clamp release to re-establish a blood supply to the newly transplanted kidney.



#### 4. CONCLUSIONS

- 4.1 The use of hypotonic intravenous solution especially 4% dextrose with 0.18 % saline has been standard practise in many paediatric unit in the U.K since the 1950s. However in the perioperative period Anti Diuretic Hormone or Vasopressin is secreted and this together with the use of hypotonic intravenous fluids can result in the development of hyponatraemia. This hyponatraemia can be associated with severe and sudden morbidity and mortality. This was recognised in the paper by Arieff et al in the BMJ 1992.
- 4.2 In a more recent article in the BMJ in 2001 by Halberthal et al. It was stated that young patients are more vulnerable to brain swelling than older children or adults. I believe therefore that there is little doubt about the causation of the acute brain swelling during the operation but I also believe that at the time of the operation it was not generally recognised that there was such a great danger involved in the use of hypotonic saline solutions.
- 4.3 In my own practice there has been one death in the early post operative period due to hyponatraemia and acute brain swelling. This is in more than 20 years practice and before the danger of hypotonic saline solution was widely recognised.
- 4.4 It is my strong belief that the surgeons involved in the operation were not responsible for the death of Adam Strain as they had no role in the decision making about the use of hypotonic saline.



- 4.5 The issue of whether the operation was carried out competently by surgeons competent to perform the procedure is obviously an important but subsidiary issue. It is likely that the patient would have died whether the kidney remained viable or not as the critical injury came during the operation following the infusion of the hypotonic saline and this was before the vascular anastomoses were completed.
- 4.6 I cannot comment on the experience of the surgeons involved in the transplant as I have no information about their degree of training or experience in the area of renal transplantation in adults or children. I would have expected the lead surgeon to have performed many transplants in adults and to be able to competently translate this skill with assistance of a paediatric surgeon into the area of paediatric renal transplant. There are very few surgeons in the UK who have much experience in paediatric renal transplantation. Many of the surgeons involved in the provision of this service actually have their major practice in adults. Paediatric renal transplantation makes up about 10% of the total renal transplants performed annually. I do not therefore believe that it was necessarily wrong for these two surgeons to be performing this operation.
- 4.7 The approach to the iliac vessels which was extra peritoneal would not have been my choice of approach but it is a perfectly acceptable approach used by some of my colleagues in children of this size.
- 4.8 The fact that the kidney appeared to change colour and become less well perfused during the operation again is a phenomenon which occurs not infrequently and usually denotes acute tubular necrosis which is a recoverable process usually caused by a prolonged storage time.

- 4.9 I would criticise all members of the multi-disciplinary team in charge of Adam's care, paediatric nephrologist, surgeons and anaesthetists for failing to check the electrolytes immediate prior to starting the operation. There is a clear entry in the notes that this should be done because of the overnight administration of intragastric hypotonic solution as well as the large number of peritoneal dialysis exchanges carried out. It is possible that the serum sodium at the beginning of the operation was already low and this may have given a warning about the use of further hypotonic solutions.
- 4.10 It is likely that the kidney infarcted soon after the operation was complete and there would probably have been either thrombosis in the renal artery or vein. This was not commented on by the pathologist carrying out the post mortem. There is no doubt in my mind that the kidney was a healthy one at the start of the operation and was potentially viable because it was competently taken from a heart beating young donor and was passing urine until the moment of removal.
- 4.11 This is a tragic case which is now unlikely to be repeated because of our improved knowledge about the use of perioperative intravenous fluid replacement. I do not think it would be prudent to blame the transplant surgeons for the death of Adam Strain.

*Mr Geoff Koffman* ..... 5.7.06

76