



MAGISTRATES COURT of TASMANIA

CORONIAL DIVISION



Record of Investigation into Death (Without Inquest)

*Coroners Act 1995
Coroners Rules 2006
Rule 11*

I, Rod Chandler, Coroner, having investigated the death of Lothar Wolfgang Kranz

Find, pursuant to section 28(1) of the *Coroners Act 1995*, that

- a) The identity of the deceased is Lothar Wolfgang Kranz;
- b) Mr Kranz was born in Germany on 29 March 1932 and was aged 85 years;
- c) Mr Kranz died at the Royal Hobart Hospital (RHH) in Hobart on 12 January 2018; and
- d) The cause of Mr Kranz's death was advanced atherosclerotic coronary artery and peripheral vascular disease complicating endovascular repair of an abdominal aortic aneurysm under general anaesthesia. Significant contributing factors were advanced centriacinar emphysema and type 2 diabetes.

Background

Mr Kranz emigrated to Australia from Germany in 1953. He was married for 57 years to Heather Vivian Kranz. They had two sons, now adults. Mr Kranz's medical history included ischaemic heart disease, chronic obstructive pulmonary disease, type 2 diabetes, anxiety and post-traumatic stress disorder.

History of Abdominal Aortic Aneurysm

In 2006 Mr Kranz was referred by his general practitioner to vascular surgeon, Dr Stuart Walker, after an incidental finding on ultrasound of an abdominal aortic aneurysm (AAA). This was successfully treated in September 2006 by endovascular repair using a bifurcated stent graft. Thereafter, his AAA was regularly monitored and in 2013 it was noted that its size had again increased. In November 2016 he underwent an embolisation procedure to occlude the feeding lumbar arteries. This was successful. However, an ultrasound scan in September 2017 showed a significant increase in the size of the AAA along with an endoleak with blood flowing between the aneurysm wall and the stent graft just below the renal arteries. This is a dangerous condition with the risk of increased pressure in the AAA sac leading to aneurysm rupture.

The options available to treat the endoleak were assessed in detail and discussed with Mr Kranz. With his approval an attempt was made on 11 October to seal the leak by

coil embolisation. However, the procedure was abandoned when it was determined that the flow of blood through the endoleak channel was too great for the treatment to be successful. This left a chimney endovascular repair as the only interventional treatment option available to Mr Kranz. Dr Walker explains the technique and the associated use of endobags in these terms:

"This is a technique that is increasingly being described in the literature to deal with AAA where the proximal neck is too short for a conventional EVR (endovascular repair) AAA or as a salvage technique to attempt treatment of type Ia endoleaks. The procedure involves deploying an extension piece above the level of the renal arteries. Clearly, if this were the only manoeuvre, the patient would die as the renal arteries would be covered and so to maintain blood supply to the kidneys (and small bowel if it is necessary to end the main body above the superior mesenteric artery), the major arteries supplying these organs are also stented. One major problem with this approach is that the combination of these multiple stent grafts in the lumen of the aorta can result in hole (gutters) between the various components and thus a risk of persistent endoleak as blood continues to flow through these gutters."

"Within the last few years, a novel technique for EVR of AAA has emerged where the stent grafts are surrounded by inflatable endobags. The idea is that the endobags fill up the lumen of the aorta and thereby reduce the risk of endoleaks. This device (Nellix by Endologic) has now been incorporated into routine practice in many centres around the world. Indeed, the device had been used a number of times with good outcomes at the Royal Hobart Hospital. This device is in theory an ideal device to use for chimney endovascular aneurysm repair as the inflated balloons would fill the gutters between the various components, reducing the chance of a persistent endoleak."

On 1 November the chimney vascular repair procedure was explained to Mr Kranz and family members. Initially he was unsure whether to proceed. However, on 29 November Mr Kranz advised Dr Walker that he wished to go ahead. Arrangements were then made for his admission to the RHH on 12 January 2018.

Circumstances Leading to Death

The procedure was undertaken on the day of admission. Dr Walker reports that the superior mesenteric artery and the renal arteries were accessed and stents successfully positioned. Similarly, both common femoral arteries were accessed and the Nellix balloon expandable stents were introduced and deployed. At this point saline was injected into the endobags for the purpose of estimating the volume of polymer required to fill the endobags and produce a seal. An angiogram then confirmed that the endoleak had been resolved with 54mls of saline. At this point the saline was removed from the endobags and polymer was introduced. However, the required pressure could not be achieved even after doubling the amount of polymer injected. It was then reasoned that the endobag on the right side probably had a leak. After additional

polymer was injected into the left endobag a further angiogram showed that the endoleak had been resolved.

Mr Krantz had been in the recovery ward for about an hour when he became hypotensive and tachycardic. Despite remedial steps his condition continued to deteriorate. It was noticed that his right leg had become very swollen and tense. The cause was not obvious but it was feared that he was developing compartment syndrome. Mr Kranz was then returned to the operating theatre and Dr Walker successfully performed right leg fasciotomies. However, Mr Kranz's condition continued to worsen and he died at 7.30pm.

Post-Mortem Examination

This was carried out by forensic pathologist, Dr Donald Ritchey. His findings included the following:

"The autopsy revealed an elderly man with advanced disease of the heart and aorta and advanced disease of the lungs caused by long-term smoking. Two atherosclerotic aneurysms were in the aorta including an approximately 6cm atherosclerotic aneurysm in the descending thoracic aorta that was intact and had not ruptured but was ulcerated and had a large wall thrombus (blood clot). A large volume atherosclerotic aneurysm of the infrarenal abdominal aorta (AAA) had a previous wire mesh graft that had a moderate amount of haematoma between the graft and the aneurysm wall as known clinically."

"There were five stents within the aorta that were appropriately positioned including stents into the right renal artery, the left renal artery and the superior mesenteric artery. Large stents from the right and left femoral arteries were also appropriately positioned. The thin plastic bags surrounding the right stent had minimal polymer and inflation with water revealed a small leak along the seam of this bag however the ultimate significance of this leak could not be determined because the bag was damaged during dissection at autopsy. The bag on the left side surrounding the stents appeared normally inflated with congealed yellow polymer."

"Biochemical testing of blood obtained prior to death excludes the possibility that death resulted from anaphylactic/o/i'd reaction. The contribution, if any, of the release of liquid polymer into the systemic circulation is unknown. Although the subsequent development of right leg pathology suggests that injury may have been caused by that event the alternate possibility of thromboembolic material emanating from ulcerated atherosclerotic plaques cannot be excluded. Microscopic sections of tissues from the right leg that developed swelling after the procedure failed to identify any emboli or foreign material."

In Dr Ritchey's opinion the cause of Mr Kranz's death was advanced atherosclerotic coronary artery and peripheral vascular disease complicating endovascular repair of an abdominal aortic aneurysm under general anaesthesia. Significant contributing factors

were advanced centriacinar emphysema and type 2 diabetes.

Investigation

This has been informed by:

1. A Police Report of Death.
2. An affidavit provided by Mrs Kranz.
3. The RHH's Death Report to Coroner.
4. A report provided by Dr Walker.
5. A report provided by Dr A J Bell as medical adviser to the coroner.
6. An email from the Medico-Legal adviser for the Tasmanian Health Service.

In his report Dr Bell advises that:

- Mr Kranz's AAA was enlarging and would ultimately rupture causing death. It was reasonable to embark on its endovascular repair.
- In his opinion the procedure was properly planned and appropriate personnel were present. The complication that arose was unexpected, unpredictable and occurred despite proper care.

Findings and Comments

It is apparent that there was a very real risk of Mr Kranz's AAA rupturing with fatal consequences and his decision therefore to undergo the EVR procedure advised by Dr Walker, despite its complexity and the associated risks, was understandable and reasonable.

The evidence shows that initially the procedure progressed without incident but this changed with the injection of the polymer. At the time it was suspected that the endobag on the right side had failed and this was confirmed at autopsy. Notwithstanding this complication, Dr Walker and his colleagues were able to achieve a sealing of the endoleak and there was good reason at this point to believe a full recovery was likely. However, there was a deterioration in Mr Kranz's condition which coincided with serious pathology affecting his right leg and despite surgical intervention Mr Kranz's death could not be avoided. The difficulties with Mr Kranz's right leg raise the very strong likelihood that they were attributable to the polymer escaping into his circulatory system but the findings at autopsy did not prove this to be so. In this circumstance, despite my suspicions, I am unable to make a positive finding that the polymer brought about the right leg pathology which caused or contributed to the death. Instead for the reasons outlined in his report I believe Dr Ritchey has correctly described the cause of death and I find accordingly.

I accept Dr Bell's opinion that Dr Walker and his support team exercised a proper level of care in the treatment of Mr Kranz and that the complication that arose during the endovascular repair procedure was unexpected and beyond their control.

I am advised that the failure of the right endobag was reported to the manufacturer and to the Therapeutic Goods Administration. The manufacturer accepts that its endobag ruptured and has caused two hazard alerts to issue. The Administration advises that it does not intend to investigate the matter further but that it “*will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.*”

I am also advised that this case was discussed by the RHH’s Vascular Morbidity and Mortality Committee and a decision was made to cease using Nellix balloon stents at the RHH for endovascular aneurysm repair. This is an understandable and appropriate result given the unfortunate outcome for Mr Kranz.

The circumstances of Mr Kranz’s death are not such as to require me to make any comments or recommendations pursuant to Section 28 of the *Coroners Act 1995*.

I convey my sincere condolences to Mr Kranz’s family and loved ones.

Dated: 24th day of April 2019 at Hobart in the State of Tasmania.

Rod Chandler
Coroner