

General Surgeon, Dr B

**A Report by the
Health and Disability Commissioner**

(Case 02HDC17107)



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Dr B	Provider / General Surgeon, a public hospital
Dr C	General Surgeon, a public hospital
Ms D	Registered Nurse, a public hospital

Complaint

On 2 November 2002 the Commissioner received a complaint from Ms A about Dr B. The complaint was summarised as follows:

Dr B did not provide services to Ms A with reasonable care and skill, in that during a Nissen fundoplication operation on 19 February 2002, he cut the aorta above the oesophageal hiatus, resulting in excessive bleeding.

An investigation was commenced on 24 January 2003.

Following expert advice the investigation was extended to include the following issue:

Dr B failed to fully inform Ms A about her condition in that he provided incorrect information about the medication he had prescribed.

Information reviewed

- Letter of complaint and accompanying documentation from Ms A, dated 1 November 2002
- Correspondence between the public hospital and Ms A forwarded by the public hospital, dated 3 February 2003
- Further information received from the public hospital, dated 10 February, 29 September and 15 October 2003
- Ms A's records, forwarded by the public hospital, dated 24 February 2003
- Letter of response to first notification and accompanying documentation from Dr B, dated 2 April 2003
- Letter of response to second notification and accompanying documentation from Dr B, dated 25 August 2003
- Relevant information received from ACC
- Transcripts of interviews with Ms A, public hospital staff, Dr C and Ms D
- Independent expert advice obtained from Dr Ian Stewart, General Surgeon.

Information gathered during investigation

Background

Ms A, aged 50 years in 2001, had a history of severe indigestion. A gastroscopy in 1995 revealed a small hiatus hernia¹ and biopsies revealed *Helicobacter pylori* (bacteria that can cause peptic ulcer) which was subsequently treated. Ms A's continuing indigestion was initially treated with Zantac, which was unsuccessful, but a subsequent change to Losec had "marvellous results" according to Ms A. Ms A's general practitioner referred her to Dr B.

The referral letter of 1 October 2001 states that Ms A "has severe GORD (gastro-oesophageal reflux disease) despite PPI (proton pump inhibitor) therapy, and Gaviscon. She has had this for many years and has a diagnosis of hiatus hernia made on gastroscopy in 1995." According to the referral letter Ms A was on Losec 20mg twice daily.

On 30 October 2001 Ms A saw Dr B. She explained her history of heartburn and oesophageal reflux (reflux of stomach contents into the oesophagus) over a five-year period. Dr B performed a gastroscopy on Ms A for "ulcer type dyspepsia and reflux symptoms" and diagnosed a hiatus hernia, without gastritis. Further, he noted that Ms A had previously suffered from a *Helicobacter* infection. Dr B suggested Ms A continue with the medication Losec, 20mg twice daily, which he planned to review in three weeks.

On 22 November Ms A again saw Dr B, who reported that she "showed an excellent response" to the medication, but told her she could not stay on Losec as it was cancer-forming. The Losec medication was then reduced to 20mg once daily and Dr B arranged a follow-up in the new year.

Information provided

On 7 February 2002, when Dr B saw Ms A again, he noted that she was not responding well to the reduction in medication, and the option of surgery was discussed. Ms A said that she had been "frightened" by Dr B telling her Losec may be cancer-forming. Ms A said that she "didn't want to stay on anything that was going to give [her] cancer of the stomach or anything" so she agreed to surgery when Dr B suggested an operation as the only solution. Dr B said that he informed Ms A that there was a theoretical risk of cancer of the stomach with prolonged acid suppression therapy and that this factor, along with the discomfort of her gastro-oesophageal reflux, led to her preference for operative treatment.

Dr B informed me:

"... [T]heories [have] led scientists to study whether or not Losec has a direct relationship with cancer of the stomach. Most studies did not show any direct correlation other than one or two notable ones linking cancer of the stomach to patients on long term Losec and who are also infected with *Helicobacter* ... other studies have

¹ Enlargement of the hole in the diaphragm through which the oesophagus passes, allowing a small part of the stomach to move up or herniate through the hole. Gastric acid enters the oesophagus and irritates the lining causing heartburn.

also shown that bacteria may be enhanced to proliferate in the stomach of individuals taking Losec.”

Dr B said that before Ms A signed the consent form he fully explained the procedure he would use, laparoscopic² Nissen fundoplication,³ and the possible need to convert the laparoscopic procedure to open surgery. Ms A was then placed on the waiting list for laparoscopic Nissen fundoplication surgery. Dr B said he appreciated that Ms A had been given a lot of information and encouraged her to ring him if, on reflection, she had any questions. Ms A said that the operation was performed within 12 days of her seeing Dr B although she was told the wait was likely to be up to six weeks.

Operation

On 19 February 2002 Ms A underwent a laparoscopic Nissen fundoplication operation. Dr B said that he used routine laparoscopic ports and a large liver retractor. Dr B conducted the surgery using a harmonic scalpel. The harmonic scalpel cuts and coagulates using ultrasonic technology. Bleeding is controlled by coagulation at low temperatures. Dr B said his technique involved first freeing the right border and under-surface of the lower oesophagus. According to Dr B’s operation record:

“Dissection progressed to the anterior oesophagus dividing the peritoneum and phreno-oesophageal ligament while inferior traction was applied to the upper stomach. The lower oesophagus was obvious at this stage and separated from the right crus and lifted anteriorly. At this point the tissue behind the lower oesophagus would appear to be all areolar tissue. Dissection then shifted toward the left side of the lower oesophagus clearing peritoneum from the left crus. We shifted from here to the left crus and the angle of His ... further areolar tissue was divided from the anterior surface of the lower oesophagus. At this point there was welling of arterial blood from the depth of the field.”

Dr B said that the blood appeared at least ten minutes after he finished the dissection of the under-surface of the oesophagus/anterior aspect of the aorta. He recorded that initially he thought the bleeding was from “the upper pole of the spleen”. However, in retrospect he thought that the bleeding came from an “unusual small direct branch from the aorta to the lower oesophagus”. Further, Dr B thought the harmonic scalpel may have temporarily coagulated this branch following the dissection.

Dr B said that he decided to convert to an open operation as the bleeding appeared to be arterial. Packing the operating field with surgical swabs temporarily stopped the bleeding. Ms A’s blood pressure was restored to a diastolic recording of over 100mmHg with a transfusion of two units of blood. Dr B said he identified the bleeding vessel as being “under the oesophagus and possibly the aorta” and Dr C’s urgent assistance was requested.

² In laparoscopic surgery small incisions into the abdominal wall enable the insertion of microsurgical instruments. One such instrument, the laparoscope (a long thin tube with a camera at one end), sends images to a video monitor. The instruments are manipulated while watching the monitor.

³ Nissen fundoplication: the upper section (fundus) of the stomach is wrapped around the oesophagus to create a one-way valve that allows food into the stomach and prevents acid going back into the oesophagus.

Ms D, scrub nurse, said that Dr B conducted the laparoscopic operation with the harmonic scalpel in one hand and grasping forceps, holding tissue out of the way, in the other. Ms D informed me that “fairly early in the dissecting stages” she was watching the monitor when the abdominal cavity filled with blood and the patient’s condition deteriorated rapidly. Ms D said that the bleeding happened “extremely suddenly” and although Dr B said they would have to open (the abdomen), this fact was very apparent to the nursing staff. Further equipment was obtained. Ms D said that “there was a huge amount of blood loss” and that they were trying to control it by applying pressure over the surgical swabs. Ms D said that the nurses asked Dr B if he wanted the assistance of Dr C, who was in the next theatre, but Dr B said he did not at that stage. Ms D said Dr B mentioned the gastric artery as the possible source of bleeding and that the nature of the bleeding meant that it was obviously arterial. The nurses again asked Dr B if he would like assistance, and Dr C was then called.

Ms D said:

“[Dr B] had no, probably, insight into how serious things were and seemed a little stunned about what was happening and reluctant to call for assistance which was only next door and that’s why the nursing staff did ask can we get help and the offer was turned down the first time and they asked again and it wasn’t until he was asked a second time that ... the nursing staff called help.”

According to Dr C’s operation note Ms A had “profuse bleeding via the oesophageal hiatus” and from the spleen, which had been partially mobilised. Further, her oesophagus had been dissected from the oesophageal hiatus and an incision had been made in the oesophageal hiatus to try to locate the bleeding.

At interview Dr C said that when he arrived at the theatre table Dr B had opened the abdominal cavity and was compressing the upper abdomen to control some arterial bleeding in the upper abdomen. Dr C said that he was not able to tell the duration of the bleeding when he arrived but he did note “there were quite a number of blood soaked packs around”.

At this stage Dr B enlarged the incision and Dr C attempted to suture what he described as “a hole in the aorta via the oesophageal hiatus”. Dr C was able to control the bleeding through the oesophageal hiatus with finger pressure on the aorta while he applied a Satinsky clamp (the Satinsky clamp partially clamps the aorta and occludes the bleeding point but at the same time allows the blood to flow down the aorta to the abdomen and other structures). Dr C said that the size and nature of the clamp gets in the way of access to the blood vessel, and better access than through the hiatus was required. Dr B then extended the incision through the left thorax and abdomen.

Dr C was able to see what he described in his operation note as a “3mm hole in the aorta approximately 3cm above the oesophageal hiatus” and repair it. He used three buttressed sutures of Prolene, and Gortex patches for the buttressing.

Following the aorta repair the spleen was found to be lacerated and bleeding uncontrollably. Dr B then proceeded to remove the spleen and perform the Nissen fundoplication.

The operation took 8.5 hours. Ms A lost 9000mls of blood and had 6500mls (13 units) of blood transfused. A total of 70 medium and 5 large swabs were used during the operation.

Location and cause of hole in the aorta

In his operation record, Dr B wrote that there was a small tear from the anterior surface of the aorta. Dr B advised me that he thought the bleeding came from “an unusual small direct branch from the aorta to the lower oesophagus”. Further, Dr B surmised that this branch may have been temporarily coagulated by the harmonic scalpel.

At interview Dr C suggested that the initial injury may have been partial, accounting for the delay before bleeding was apparent. Further, that if a divided blood vessel was not sufficiently coagulated with the harmonic scalpel it could subsequently bleed. However, Dr C advised me that he did not think the injury he saw was caused in that manner. Dr C said he did not see signs of burn around the hole and it is usual to see “something nearby that’s been partially coagulated (like a cooking effect) with the harmonic scalpel”. Dr C said he thought it more likely that a branch of the aorta had been torn off in some way by a grasping or dissecting instrument, causing the hole. He stated that:

“[t]he anatomy of the blood supply in the chest is variable, the ... anterior part of the aorta does not commonly have any major blood vessels but not uncommonly has minor ones that supply the oesophagus and the diaphragm and it could well be that there was an abnormally large blood vessel at that point.”

Dr C noted that variation in the anatomy can reasonably be expected in this area.

Ms D recalled Dr B saying that he might have hit the gastric artery. However, once Dr C had cleared the operating field she could see a definite hole in the aorta, with arterial blood coming out. Ms D said that she presumed the hole was made with the harmonic scalpel as Dr B was dissecting. She did not think that the grasping forceps could have made the hole.

Ms A said Dr B gave her the following explanation:

“He had come round a corner and there was a little thing there that should not have been and he had nipped it and I don’t think at any stage he actually said my aorta. It was just a little thing and that shouldn’t have been there”

Post-operation

Ms A was transferred to intensive care, where she was ventilated until 20 February. She remained in the intensive care unit for five days following the operation. Ms A said that during this time she was “absolutely petrified” of what was happening around her. Beyond telling Ms A that he had “nipped” something, Dr B explained only that he and Dr C had also removed her spleen, which had been damaged. Dr B drew Ms A a diagram, which she said she could not understand. Ms A found Dr B very hard to understand, and other

members of staff had to provide her with the information she required to fully appreciate what had happened to her.

On 25 February Ms A was transferred to the surgical ward and discharged from there five days later on 2 March.

Ms A now suffers from continuing post-thoracotomy (surgical incision of the chest wall) pain and is awaiting further surgery. At interview Ms A said the after-effects of the operation have had a devastating effect on her and her partner. She said:

“... I can’t sit for any length of time, I lie in chairs the way I’m doing now. For me to sit up straight at 20 minutes, so it means we can’t, haven’t been really able to travel. I’ve got family in [a town] that we can’t, they have to come to us because by the time we get to [a town] I’m not worth a tin of fish. I’m sore and what have you.”

Actions taken following the operation

Following Ms A’s operation Dr B reported:

“I do sympathise with what [Ms A] went through. What happened was unfortunate and I feel the artery concerned was so small and its presence not common. I was devastated that [Ms A] had suffered this mishap. I reviewed the incident with colleagues and was reassured that this could have happened to other surgeons. This was not enough for me to wish to do the procedure again without review. An ongoing issue as a surgeon in a small hospital is firstly that we have to be generalist in our specialty practice and therefore would not have the experience in any one procedure that a surgeon, for example in [a city], who does only a few types of surgery. Secondly we are not exposed to the cases, discussions of any one type of procedure that our colleagues in major centres can access.

To ensure that I was up to date in my skills I sought agreement with management that

- (a) I would cease doing laparoscopic Nissen funduplications.
- (b) I have attended a session with [...] at [an endoscopy and laparoscopy unit]. I chose him as I believed he does more of these procedures than anyone else in the country. I arranged to attend further sessions from time to time.
- (c) This event was so upsetting that I do not wish to carry out this procedure again without a very experienced specialist on hand. Although it was reassuring to observe [...], I still wish to have what is in effect a mini exam and this will occur when I next perform the procedure. In fact my next at least one, and maybe more, Nissen funduplications will only be performed if another very experienced super specialist is present and able to critique and assist. I will only perform this procedure on my own once I have positive comment from my observer, and once I feel confident to do so.”

ACC

ACC accepted that owing to the rarity and severity of her injury, Ms A suffered a personal injury as a result of medical mishap. The ACC expert advisor found no obvious indication of medical error.

Independent advice to the Commissioner

Initial advice

The following expert advice was received from Dr Ian Stewart, general surgeon, on 30 June 2003:

“In the submitted documents I was able to view the letter of complaint from [Ms A], the ACC deliberations (including the summary from Dr [...]), the operative description from [Dr B] and [Dr C] and the numerous [public hospital] notes, including outpatient visits.

1. [Dr B's] description of his laparoscopic fundoplication procedure to the point he converted to an open operation seems quite standard. He had mobilised the distal oesophagus normally taking it clear of the diaphragmatic crura in preparation for a cruroplasty. He used the harmonic scalpel for this dissection, an instrument commonly used in upper gastrointestinal surgery, particularly laparoscopic work. Ironically, the harmonic scalpel is thought to offer greater protection than other diathermy techniques from inadvertent bleeding problems. There is nothing in the description of the operation to suggest an unsatisfactory surgical method.
2. Catastrophic bleeding during laparoscopic fundoplication is extremely rare. Most reports in the literature of major vascular injury are simple case reports and there are very few of them. Injuries to the inferior vena cavae, left hepatic vein, the aorta and inferior phrenic vessels have all been reported. (Br.J.Surg. 1997 : 84 : 556-557). A recent report (Surg.Endoscopy 2002 Feb : 16 (2) (362) described an aortic injury during laparoscopic fundoplication and the patient died.

In the lower part of the thorax the oesophagus is placed in front of the aorta and as it moves through the diaphragm the oesophagus moves anteriorly and to the left of the aorta. A variable number (usually 4 or 5) of arteries arise from the front of the thoracic aorta and supply the oesophagus. These branches usually form a vascular chain that anastomoses with oesophageal branches from the inferior thyroid artery above and the left phrenic and left gastric arteries below.

Whilst it would be relatively easy to accidentally divide one of these smaller lower anastomotic branches it would be extremely rare to ‘divide and clip’ a direct aortic branch. The main direct oesophageal aortic branches arrive from the thoracic aorta and would usually be well out of the operative field during this surgery. However,

aberrant vessels conceivably could arise from the front of the aorta as it descends through the diaphragm as [Dr B] suggests.

The operative findings and summaries from [Dr B] and [Dr C] are different in that [Dr B] describes a possible oesophageal branch of the aorta as the bleeding vessel whilst [Dr C] refers to a 3mm hole in the front of the aorta. The observation that it took 10 – 15 minutes for the bleeding to become apparent is difficult to explain in either scenario (that is a divided branch, or a direct hole in the aorta). Potentially, some forceful retraction on the aorta initially masked the bleeding site, but I think more likely bleeding from either of the two described bleeding sites would have begun and become very obvious immediately.

Once the bleeding problem was seen appropriate procedures took place to resolve the problem. Particularly [Dr B] converted the procedure to an open operation and secondly, he called for the assistance of a second surgeon. A catastrophic bleed of this magnitude is enormously stressful to the surgeon and assisting staff and it is vital in this setting to call for assistance and this was done.

3. I believe the actions then of [Dr B] and [Dr C] were entirely appropriate – they firstly gained control of the blood loss by packing and pressure and then gained better exposure by extending the wound to a thoracotomy. This gave good access to the bleeding site and [Dr C] repaired the defect.
4. Whilst some kind of unfortunate circumstance such as –
 - i) ‘failure’ of the harmonic scalpel;
 - ii) aberrant (unexpected) anatomy

could explain this complication, I think this is unlikely.

[Dr C’s] evidence of repairing a hole (3mm) in the front of the aorta would largely refute either of the above.

Whilst accidents do occur that don’t necessarily reflect a lack of reasonable care and skill, I believe to injure the aorta at this surgery is potentially such a severe complication, it cannot be viewed as just unfortunate. Should [Dr B] have done many of these procedures without any problems, then perhaps this complication can be viewed more sympathetically, although it still comes under the definition of lacking reasonable care and skill.

If [Dr B] has limited experience (or training) with this operation, then this type of complication reflects a lack of awareness of the potential pitfalls (the proximity of the aorta, the use of the harmonic scalpel etc.), and he should not do this procedure. The most likely explanation for the injury would be due to a failure to understand the anatomy and recognise the plane of dissection. Failure in either situation, indicates a need to stop and re-evaluate before proceeding.

5. My only other comment in this case concerns [Ms A's] assertions over why she consented to the procedure. She states 'this only happened after he spoke with me about Losec being cancer-forming ...'. From what she says, she clearly felt compelled to have the surgery because of this risk. This comment is at variance to what [Dr B] documents. He said in his submission that he told her there was 'a theoretical risk of cancer of the stomach', 'a small risk of cancer'. I clearly can't comment on what was actually said in that pre-operative discussion but it should be emphasised there are no safety issues with Losec. As recently reported (Clinical Gastroenterology and Hepatology 2003 : 1 : 81-88) there have been no reports of tumours or important side effects of Losec after over a decade of extensive clinical usage. Antireflux surgery should not be indicated on the premise that long term antireflux medication will predispose to cancer.

Summary

Despite [Dr B's] implication that aberrant anatomy or failure of the harmonic scalpel was the cause, the evidence documented would suggest otherwise. It seems most likely he failed to recognise how close his dissection was to the aorta. The consequences of this failure can be catastrophic (and they nearly were in this case) and reflect a standard of care inferior to what would be expected."

Further advice

After consideration of the interviews with the public hospital staff and Ms A, Dr Ian Stewart provided the following statement, received on 4 November 2003:

"My name is Dr Ian David Stewart. I am a general and endoscopic surgeon at North Shore Hospital, Auckland. I have considerable experience in laparoscopic cholecystectomy and appendicectomy and am experienced in port insertion in laparoscopic surgery.

I have considered the additional information supplied concerning the operation of [Ms A] on 19 February 2002 obtained from transcripts of interviews between [Ms A], [Dr C], [Ms D], and investigation officers with the Health and Disability Commissioner.

Lacerated spleen

A lacerated spleen is a well recognised complication of operating in the upper abdomen. This is not an unusual complication but it is thought that since laparoscopic anti-reflux surgery has developed the spleen has suffered less.

Trauma to the aorta

My understanding of the anatomy is that there are no recognised or named branches from the aorta going to the oesophagus at that level. Having said that, and [Dr C] endorses this, there's quite a variation in what branches come off these vessels and probably small aberrant vessels can arise from there. I looked at the reports to try and see some evidence that there might have been a small vessel, in other words was there a stump of a vessel? There is nothing in the observation by either surgeon to suggest there was a vessel stump. The surgeons just referred to a 3mm hole in front of the aorta.

If the aberrant vessel theory is correct, then it is surprising there is no evidence of a vessel stump.

Understanding of anatomy

There is a close relationship between the back of the oesophagus, the aorta behind it and the crura, the muscles that arch on either side to allow the oesophagus to come through. I would think that you would have to lose your way by quite a bit to end up injuring the aorta. In the last five years I haven't done this surgery but I have looked up some recent literature on this and certainly injuries such as this have been reported. We don't know about those that haven't been reported. When you are operating on the oesophagus and the crura, and close to the aorta, then providing there is not a lot of bleeding and not a big hernia in the way, it would be reasonable to expect [Dr B] to be aware of where the aorta is.

Calling for assistance

In regards to how long a surgeon would wait before calling another surgeon for assistance usually the surgeon himself can usually deal with the bleeding that occurs, for example from the spleen. I think [Dr B] thought initially that the spleen was the problem. That is stressful enough and I think any sort of delay would have been just him trying to get some feel for what was going on. Most of the time he would have been able to handle it fine himself. My interpretation was that once he realised there was a significant bleed occurring then the correct procedures were done. He converted the operation to an open procedure and he called for [Dr C].

I found no evidence that [Dr B] was reluctant to call [Dr C] . The natural response when some significant bleeding or complication occurs is for the surgeon to find exactly what's going on. It is highly unusual for the aorta to be the source of the bleeding, as in this case. [Dr B] probably thought that it may have been something like the left gastric artery or indeed the spleen, both of which I'm sure he could handle himself. I think until [Dr C] arrived, [Dr B] still did not know that it was the aorta. However, he called [Dr C] because he was unable to control the bleeding.

Losec

When Losec first came out there was some doubt based on theoretical grounds about its carcinogenic status. I sought the opinion of a respected gastroenterologist who referred me to recent literature, indicating there are no concerns with the use of long term Losec.

My criticism is simply based on the fact that it is wrong to use any perceived carcinogenic theory of Losec, as a reason to have anti-reflux surgery. Certainly failure by Losec, or proton pump inhibitors to control reflux symptoms can be an indication for surgery.”

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

- 1) *Every consumer has the right to have services provided with reasonable care and skill.*

RIGHT 6

Right to be Fully Informed

- 1) *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –*
 - a) *An explanation of his or her condition; and*
 - b) *An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; ...*

RIGHT 7

Right to Make an Informed Choice and Give Informed Consent

- 1) *Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.*
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Opinion: Breach – Dr B

Management of Ms A's condition

At her consultation with Dr B on 22 November 2001, Ms A said that Dr B told her that her recent gastroscopy revealed a sliding hiatus hernia. Dr B reduced by half the amount of Losec Ms A had been taking. Ms A said Dr B told her that she could not stay on Losec as it was cancer-forming. Dr B stated that he informed Ms A that there was a theoretical risk of stomach cancer with prolonged acid suppression. Dr B believed that “one or two notable [research studies]” linked stomach cancer, long-term Losec medication and infection with *Helicobacter*. It is clear that Dr B advised Ms A that she should not stay on Losec long term, as there was a risk of stomach cancer.

On 7 February 2002 Ms A again consulted Dr B as her ongoing indigestion had been exacerbated by the reduction in Losec. Dr B told Ms A that she could have the hiatus hernia surgically corrected. Ms A agreed to proceed with the operation as she felt that surgery was the best option for treatment based on her understanding that Losec was cancer-forming.

I note my expert advice that there have been no reports of cancer as a result of taking Losec. In relation to any perceived cancer-causing properties of Losec, my expert advisor commented:

“I sought the opinion of a respected gastroenterologist who referred me to recent literature, indicating there are no concerns with the use of long term Losec.”

My expert advisor also noted:

“It is wrong to use any perceived carcinogenic theory of Losec as a reason to have antireflux surgery.”

Dr B considers that he gave Ms A correct advice. My expert advisor does not agree. I accept my expert advice that antireflux surgery should not be recommended on the premise that long-term antireflux medication will predispose to cancer.

In my opinion Dr B failed to exercise reasonable care and skill in his management of Ms A’s condition. Dr B informed Ms A that the prolonged use of the medication she was taking could be cancer-forming. This information was incorrect. On the basis of that misinformation, Ms A elected to undergo surgery, which had and continues to have a major impact on her life. In these circumstances, Dr B breached Rights 4(1), 6(1)(b) and 7(1) of the Code.

Surgical intervention

In his operation note Dr B recorded a small tear from the anterior surface of the aorta. Dr B said that in retrospect he thought the bleeding came from an “unusual small direct branch from the aorta to the lower oesophagus”. He thought that the harmonic scalpel may have temporarily coagulated this branch following dissection.

Dr C recorded in the operation note his observation that there was “a 3mm hole in the aorta approximately 3cm above the oesophageal hiatus”. Dr C said he thought that it was possible that there was a branch of the aorta that was torn off in some way and that the size of the hole suggested that this was abnormal anatomy. However, he did not see any signs of coagulation around the hole, which he would have expected if the harmonic scalpel had caused the hole.

Ms D said that once Dr C cleared the operating field she could see a definite hole in the aorta. Ms A said Dr B explained to her that “there was a little thing there that should not have been and he nipped it”.

I note the advice from my independent expert:

“Whilst it would be relatively easy to accidentally divide one of these smaller lower anastomotic branches it would be extremely rare to ‘divide and clip’ a direct aortic branch. The main direct oesophageal aortic branches arrive from the thoracic aorta and would usually be well out of the operative field during this surgery. However, aberrant

vessels conceivably could arise from the front of the aorta as it descends through the diaphragm as [Dr B] suggests.”

My expert further advised that while “failure” of the harmonic scalpel or aberrant (unexpected) anatomy could explain this complication, it was unlikely and that “[Dr C’s] evidence of repairing a hole (3mm) in the front of the aorta would largely refute either of the above”.

Dr B said that the blood appeared at least 10 minutes after he finished dissection of the under surface of the oesophagus/anterior aspect of the aorta. Ms D, scrub nurse, said she was watching the television monitor, where the operation was simultaneously screened, and that “fairly early in the dissecting stages” the abdominal cavity filled with blood and Ms A’s condition deteriorated rapidly. She said the bleeding happened “extremely suddenly”.

My expert advised that if, as Dr B described, it took 10 to 15 minutes for the bleeding to become apparent, it is difficult to explain the fact that the bleeding point was an oesophageal branch of the aorta or a 3mm hole in the front of the aorta. I accept my expert advice that bleeding from either of the two described bleeding sites would have begun and become very obvious immediately.

I note my expert advice that Dr C’s evidence of repairing a hole in front of the aorta would largely refute the “failure” of the harmonic scalpel or aberrant anatomy and that bleeding would have been immediately apparent. I therefore conclude that it is probable that Dr B directly injured the aorta while undertaking the Nissen fundoplication.

Dr B stated that a Nissen fundoplication operation is not one with which he has a lot of experience. He explained that the public hospital is small and he has to be a generalist in his specialty practice.

I note my expert’s comment:

“Whilst accidents do occur that don’t necessarily reflect a lack of reasonable care and skill, I believe to injure the aorta at this surgery is potentially such a severe complication, it cannot be viewed as just unfortunate. ... The most likely explanation for the injury would be due to a failure to understand the anatomy and recognise the plane of dissection.”

I accept my expert advice that such a severe complication cannot be viewed as simply unfortunate. Dr B had limited experience with the particular operation. The complication reflects a lack of awareness of the potential pitfalls and a failure to understand the anatomical plane of dissection. It appears that Dr B failed to recognise how close his dissection was to the aorta and that the complications Ms A suffered during this operation resulted from lack of reasonable care and skill. Accordingly, Dr B breached Right 4(1) of the Code.

Opinion: No breach – Dr B*Gaining control of the bleeding*

Dr B's surgical technique involved freeing the lower oesophagus by dissecting the surrounding tissues laparoscopically. Dr B converted from a laparoscopic to an open operation when unexpected bleeding appeared to be arterial. He packed the operating field with surgical swabs temporarily to stop the bleeding. Ms A's blood pressure was stabilised with a blood transfusion. The circulating nurse asked Dr B twice if he wanted assistance from Dr C. Although the offer was turned down the first time, Dr C was called into the operating theatre the second time.

I accept my expert advice that a catastrophic bleed of this magnitude is enormously stressful to the surgeon and assisting staff. Once the bleeding problem was seen, appropriate procedures took place to resolve the problem, including converting the procedure to an open operation and calling for the assistance of a second surgeon. I am satisfied that the actions of Dr B and Dr C were entirely appropriate – gaining control of the blood loss by packing and pressure and then extending the wound to a thoracotomy.

Opinion: No vicarious liability – A District Health Board

Employers are vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. However, under section 72(5) an employing authority has a defence if it shows that it took such steps as were reasonably practicable to prevent an employee from breaching the Code.

Dr B breached Rights 4(1), 6(1)(b) and 7(1) of the Code. In my opinion, the District Health Board responded appropriately to the concerns in this case. The DHB had credentialling processes in place for senior medical staff in an attempt to ensure continuing competence.

Following Ms A's operation Dr B and the DHB agreed that Dr B would cease doing Nissen fundoplication operations, observe the operation at an Endoscopy and Laparoscopy Unit and carry out the procedure only following a competency assessment from a senior and experienced surgeon. When notified in writing of problems concerning Dr B, the DHB requested the New Zealand Medical Council, on 23 December 2002, to conduct a review of Dr B's competence. In these circumstances, the DHB is not vicariously liable for Dr B's breaches of the Code.

Comments

Explanation of complication

Ms A suffered a very serious complication of her surgery. In relation to the hole in her aorta, Dr B told Ms A only that he “nipped” a little thing that should not have been there. Dr B did not mention that the aorta, a major blood vessel, was involved. In such a situation it is important to take special care with information provision. An explanation of the reasons for a major surgical complication is information that a reasonable patient would expect to receive, and is entitled to pursuant to Right 6(1) of the Code. Ms A required substantial information following her very frightening experience and found Dr B difficult to understand. In this situation it was important for Dr B to take time to ensure that Ms A understood what had happened to her.

Competence review

During the course of my investigation I asked the Medical Council of New Zealand about the outcome of Dr B’s competence review. The Medical Council requested that I seek the information from Dr B. My request to Dr B (via his legal counsel) for the results of the review was declined. The Medical Council has since advised that there is a condition on Dr B’s practice which states that he will undertake his competence programme in a position approved by the Council’s Medical Advisor. The district health board has informed me that Dr B is no longer working there.

Contemporaneous investigation

I note that a contemporaneous investigation of Dr B’s surgery on another patient at the public hospital also resulted in breach findings: HDC Case 02/14386, 24 March 2004.

Follow-up actions

- I have referred this matter to the Director of Proceedings in accordance with section 45(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any further action should be taken in relation to Dr B.
- A copy of this report will be sent to the Medical Council of New Zealand, the Royal Australasian College of Surgeons, and the Director-General of Health.
- A copy of this report, with identifying features removed, will be sent to the Royal Australasian College of Surgeons and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes, upon completion of the Director of Proceedings’ processes.

Addendum

At a hearing before the Health Practitioners Disciplinary Tribunal on 19 September 2005, Dr B admitted a charge of professional misconduct, which was upheld by the Tribunal. Dr B was censured and ordered to practise under conditions, that is, that he is supervised for a period for two years from the date of the hearing. A contribution of 25% costs or \$20,000 (whichever was the lesser) was also ordered. The Tribunal lifted the interim name suppression order, but Dr B appealed on the question of final name suppression and has been granted further interim name suppression pending the hearing of that appeal.
