Obstetrician and Gynaecologist, Dr B

A Report by the Health and Disability Commissioner

(Case 08HDC08586)



Overview

On 10 May 2005, gynaecologist Dr B performed a laparoscopic operation¹ on Ms A (then aged 37 years) to treat a gynaecological condition and prevent future pregnancy. A complication occurred when Dr B's left iliac fossa² port went through one of Ms A's arteries. Dr B recognised the complication immediately. She controlled the bleeding and continued the operation as planned. Soon after the surgery, Dr B informed Ms A about the complication.

Postoperatively, Ms A did not recover as expected. She was uncomfortable and troubled by pain. Ms A consulted her general practitioner a number of times, attended follow-up appointments with Dr B, and underwent three ultrasound scans. On 15 August 2005, a pseudoaneurysm³ in the region of Ms A's left iliac fossa was diagnosed.

On 1 September 2005, vascular and general surgeon Dr D found and surgically repaired a 3cm pseudoaneurysm on Ms A's left inferior epigastric artery.⁴ Her recovery from this operation was uneventful.

It is well understood that every surgical operation carries a risk of complication. Doctors have a duty of candour and patients have a right to full disclosure when something goes wrong during an operation. This opinion focuses on the adequacy of the information Dr B provided to Ms A following the complication during her gynaecological surgery. In my view, Dr B breached her duty of candour to Ms A.

Complaint and investigation

The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by Dr B. The following issues were identified for investigation:

- The appropriateness of the care provided by Dr B to Ms A between December 2004 and August 2005.
- The adequacy of the information provided by Dr B to Ms A between December 2004 and August 2005.



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¹ Laparoscopic surgery, commonly known as keyhole surgery, is performed using tubular instruments that are passed through small incisions in the wall of the abdomen. A small camera inserted through one of the ports allows the surgeon to view the patient's internal anatomy and perform the procedure/s. ² The left iliac fossa is part of the internal surface of the left hip bone.

³ A true aneurysm is a balloon-like swelling in the wall of an artery. A pseudoaneurysm (or false aneurysm) is a condition where the entire arterial wall is injured and blood is retained in the surrounding tissues. A pseudoaneurysm is caused by damage to one or more layers of the artery as a result of arterial trauma or the rupture of a true aneurysm.

⁴ The left inferior epigastric artery is an artery in the region of the left hip.

An investigation was commenced on 5 September 2008.

Parties involved

Ms A Dr B	Consumer Obstetrician and gynaecologist/Provider
Dr C	General practitioner
Dr D	Vascular and general surgeon

Information was reviewed from:

Ms A Dr B Dr C Dr D A private hospital

Independent expert advice was obtained from obstetrician and gynaecologist Dr Tal Jacobson (see Appendix 1). Dr B submitted expert advice from gynaecologist Dr John Tait and vascular and endovascular surgeon Dr Richard Evans.

Information gathered during investigation

Background

Ms A, then aged 37 years, first consulted gynaecologist Dr B on 2 December 2004 with a history of heavy and painful periods. She had decided that she did not wish to have children. After considering a range of treatment options and perusing written information provided by Dr B, Ms A consented to a laparoscopic Filshie clip sterilisation⁵ and hysteroscopic endometrial resection⁶ to treat her gynaecological condition and prevent pregnancy in the future.

10 May 2005 surgery — the private hospital

On 10 May 2005, Dr B performed the surgery on Ms A. During the laparoscopy, the left iliac fossa (LIF) port went through one of Ms A's arteries. Dr B recognised the complication immediately. She controlled the bleeding by inserting two further ports and placing two figure-of-eight stitches laparoscopically. In her operation note Dr B recorded:

⁶ A hysteroscopic endometrial resection is the surgical removal of a portion of the mucous membrane lining the uterus using a tubular instrument passed through the vagina and into the uterus.



⁵ A Filshie clip sterilisation procedure prevents future pregnancy by closing the Fallopian tubes with a small clip/s. This operation is performed laparoscopically using tubular instruments passed through small incisions in the wall of the abdomen.

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"**Procedure:** complicated laparoscopy. 10mm central camera port went in fine without complications. The left sided 5mm LIF port went thru' an arteriole — bleed = 200mls+. Therefore extra x 2 5mm ports quickly applied and laparoscopic figure of 8 sutures x 2 with 1 vicril used to obtain haemostatic sutures — Haemostasis around the port site here was fully obtained at this point."

Once Dr B had controlled the bleeding, she proceeded with the surgery. She found a cyst of approximately 4cm in diameter on Ms A's left ovary and suspected it was the cause of her pain in that region. Dr B aspirated the fluid from the cyst, and the ovary collapsed back to its normal size. Dr B found that Ms A's left ovary was otherwise normal, as was her right ovary, Fallopian tubes, and pouch of Douglas (POD).⁷ In her operation note, Dr B recorded:

"Findings: then large left follicular ovarian cyst noted about 4 cm d". This cyst was aspirated — clear yellow fluid aspirated. Ovary collapsed back to normal size. Otherwise normal ovary. The right ovary was normal. Tubes and POD normal. The left follicular cyst was probably the cause of the pain patient has been complaining of in that site."

Dr B then applied two Filshie clips to each of Ms A's fallopian tubes to prevent future pregnancy. She explained that she routinely applies two Filshie clips to each Fallopian tube to reduce the risk that the clips fail as a means of reproductive sterilisation. Dr B checked the placement of the clips, before irrigating and cleaning Ms A's pelvis. At the completion of the surgery, Dr B was satisfied that she had achieved "full haemostasis".⁸ She recorded:

"**Then Filshie clips X 2 FOR EACH FALLOPIAN TUBE** applied thru midline 1 cm port site that was required for the Filshie clip applicator. Clips checked, appropriately applied, not loose, well tight, and covering full breadth of the tube. Pelvis irrigated and cleaned. FULL HAEMOSTASIS on camera — recorded."⁹

On the operation note, Dr B recorded that it was to be copied to the ward and her rooms, as well as to Ms A and her general practitioner, Dr C.

The clinical record also contains a series of still laparoscopic photographs that were taken during the operation.

Postoperative period

Ms A was transferred from theatre to the Post Anaesthetic Care Unit where she was cared for from 3pm. During this time, Ms A was given pain relief and intravenous fluids and her observations were noted to be stable. She was transferred to the ward at 4.15pm and her condition remained stable overnight. According to the clinical record,



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⁷ The pouch of Douglas is a pouch accompanying the space between the rectum and the uterus.

⁸ "Full haemostasis" means that all bleeding has stopped.

⁹ HDC was provided with still photographs, but no video footage of the operation.

Ms A was tolerating a light diet, her abdominal wounds were satisfactory and she was progressing as expected.

At some time during Ms A's recovery on the ward, Dr B visited her to discuss the surgery and check her progress. Ms A's husband was also present at this time. According to an undated nursing note, Dr B explained to Ms A and Mr A that during the operation, she had accidentally cut an "aberrant" blood vessel. Dr B described the steps she took to stem the bleeding, including the application of two extra ports. She informed Ms A that she could expect additional bruising as a result of the complication.

A nurse discharged Ms A from hospital on 11 May 2005, and recorded this process on a discharge summary sheet. In the section for recording specific patient discharge advice, the nurse recorded: "Refer to [Dr B's] discharge advice sheet." Dr B's discharge advice was contained in her operation record. Here Dr B advised Ms A:

"THE LEFT WOUND MAY LOOK VERY BRUISED AND SWOLLEN FOR A WEEK / TWO BUT WILL SETTLE. Tenderness over this wound may persist for a few weeks. This is because of the bleeding that occurred and had to be adequately repaired at this site."

Ms A was booked to see Dr B for a follow-up consultation on 28 June 2005, seven weeks after her operation. She was discharged home to the care of Dr C.

Loss of Ms A's electronic notes

Dr B explained that approximately two months prior to Ms A's operation, she began the transition to an electronic record-keeping system. During the transition phase, Dr B's nurses occasionally missed a crucial step in the electronic record storage process, resulting in the loss of patients' notes unless they could be retrieved close to the time. Dr B "distinctly [remembers]" writing additional electronic notes for Ms A. However, she said that a nurse did not save these notes properly and they could not be retrieved because the nurse did not report the storage error in time. Dr B has apologised "[f]or this error of the system and chain of reporting".

Phone follow-up

In the week following the operation, Ms A was uncomfortable and troubled by pain. She recalls that Dr B's nurse called her one week after the operation to see how she was, and again once she heard that Ms A had presented to her general practitioner.

On 13 May 2005, Dr B received a medical laboratory report advising that the tissue removed from Ms A during the operation showed no evidence of malignancy. Dr B asked her nurse to call Ms A to check her progress with recovery and advise her of the laboratory result. An undated and unsigned note on the laboratory result confirms that this call was made.

Ms A's presentation to her general practitioner and the first ultrasound scan

Ms A consulted her general practitioner, Dr C, on 17 and 20 May 2005. Dr C observed that Ms A's abdomen was firm, and that she was experiencing pain around

the left laparoscopic wound site and in the abdominal area. In light of these observations, Dr C prescribed antibiotics for Ms A.

On 30 May 2005, Ms A consulted Dr C again because although she had experienced some improvement with antibiotics, her pain had increased. Dr C observed that Ms A's left lower abdomen was tender and there were some palpable lumps under her skin. She prescribed a further course of antibiotics and referred Ms A for an ultrasound.

On 2 June 2005, a radiologist reviewed Ms A's ultrasound scan and found a cyst containing complex fluid on the left ovary. He reported his findings to Dr C and Dr B.

Follow-up appointments with Dr B and two further ultrasound scans

On receipt of a copy of the radiology report, Dr B arranged to see Ms A on 9 June 2005. At this appointment, Dr B performed an ultrasound scan at her rooms to check for a common problem such as a haematoma¹⁰ or abscess. The scan revealed a 2cm diameter haematoma in the abdominal wall at the LIF port incision site. Dr B found that the haematoma was "slowly resolving [and] most likely intramuscular". Among other observations, Dr B noted that the small fluid collection on Ms A's left side was now less than 2cm in diameter, and there was no fluid behind her uterus in the POD. The plan was for Ms A to take anti-inflammatories and regular antibiotics for two weeks, before another follow-up appointment.

Ms A's next appointment with Dr B took place on 23 June 2005. Dr B reported to Dr C that "[t]hings have now come right". She noted that Ms A had some postoperative bruising, muscle tenderness, and some residual pubic tubercular¹¹ pain. Dr B queried whether this could be mild osteitis¹² or a mild ligament pull. Otherwise, she considered there were "no further sequelae of note clinically speaking". Dr B offered one last further review in three months' time.

Over the next month, Ms A experienced ongoing pain and tenderness so she returned to see Dr B on 28 July 2005. Dr B observed that there was no overt evidence of haematoma but there was some nodular scarring¹³ and tenderness. She queried whether there were any ongoing musculoskeletal injuries, and referred Ms A to a practitioner for physiotherapy, acupuncture and massage to help any musculoskeletal pain in the area. Dr B also referred Ms A to a sports medicine specialist for a further opinion and assistance.

Ms A does not recall the referral for physiotherapy, acupuncture and massage. She decided not to make an appointment with the sports medicine specialist because she was already working with a Pilates instructor who specialises in treating clients who have had sporting and other accidental injuries. Ms A had confidence in her Pilates instructor, and she was unconvinced about the benefit of seeing the sports medicine



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¹⁰ A haematoma is an accumulation of blood within the tissues that clots to form a solid swelling.

¹¹ A tubercle is a small round growth found on bones or skin, which can grow on the genitalia.

¹² Osteitis is the inflammation of bone due to infection, damage, or a metabolic disorder.

¹³ Nodular scarring refers to small swellings or knots of scar tissue.

²³ November 2009

specialist. By this time, Ms A was also becoming concerned about the ongoing cost of treatment.

However, Ms A's ongoing pain and discomfort did not resolve following the appointment on 28 July 2005 so she contacted Dr B again. Dr B arranged a further ultrasound scan, which was performed on 15 August 2005. A radiologist reviewed the scan and reported that there appeared to be a left iliac fossa pseudoaneurysm.

Referral to vascular and general surgeon Dr D

Dr B contacted vascular and general surgeon Dr D on receipt of the radiology report to obtain his opinion on the pseudoaneurysm finding. Although there is no direct written record of what was said during their conversation, Dr B recalls that Dr D informed her that pseudoaneurysms of this kind are very rare. She recalls his advice that Ms A's pseudoaneurysm was not at immediate risk of rupture because it was likely to be small, the area was well compressed in tight compacted tissue, there was already a suture around the artery, and it appeared not to be leaking. Dr B states that Dr D advised her to tell Ms A that her pseudoaneurysm was unlikely to rupture.

On 16 August 2005, Dr B called Ms A to advise her of the ultrasound findings, explain the nature of the pseudoaneurysm, and discuss treatment options. Dr B then referred Ms A to Dr D by email. Dr B copied this referral email to Ms A. It read:

"Dear [Dr D]

•••

Please could you see [Ms A] for advice and assessment. She has been found on a recent [ultrasound scan] to have a pseudo-aneurysm possibly in the region of the superior epigastric artery or one of its smaller branches. I am not sure if this anatomy predates the operation or is as a result of the emergency stitch required to stop the bleeding.

She has had an endometrial ablation and laparoscopic Filshie clip sterilization with me on 10th May 2005. She had a sudden and brisk bleed from the LIF port fairly soon after port insertion and I had to put 2 emergency figure of 8 sutures at the time. These were done laparoscopically at the time and immediately and they successfully controlled the bleed. Initial recovery was normal. Since she has had niggly pains and a tautness in the area ... for a few weeks now. I have gone through a trial of antibiotics and a trial of anti inflammatories with some success but not a whole lot.

I have referred her for physiotherapy and massage as conservative means to help any musculoskeletal pains in the area. I am asking for your advice and opinion and help as well in this matter. I have rung [her] indicating that I would like to refer her to you for assessment. She will be away [overseas] for a couple of weeks but would appreciate an appointment soon after her return.

I have indicated to her based on our chat today regarding the [ultrasound scan] report that there are a few options, conservative, exploratory ligation and

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thrombotic. I have also indicated that it is probably not an acute issue that needs to be worried about too much and immediately.

She is now surgically over 3 months post operation and internally should be fully healed.

Many thanks for seeing her.

...,"

Email correspondence regarding Ms A's concerns

On 17 August 2005, Ms A emailed Dr B thanking her for the referral to Dr D but expressing her frustration at "the whole situation". Ms A felt that Dr B's postoperative follow-up care had been inadequate. She said that she had only received further care because she has asked for it and persisted. While Ms A appreciated that Dr B was busy, she emphasised that "caring for existing patients, who have had complications and are in pain should be really important". Ms A said that she expected more for the \$13,000 paid by her insurance company to a private healthcare provider.

Ms A also expressed her frustration at the length of time and number of scans it took to properly diagnose her pseudoaneurysm. With specific reference to Dr B's email referral to Dr D, Ms A asked:

"Do you genuinely believe this aneurysm was present before the surgery? This seems highly unlikely and feels like you are trying to avoid responsibility. I have accepted all along that surgery has risks and have only sought resolution rather than place blame, so I'm not sure why you found it necessary to include this statement in your referral to [Dr D]."

Finally, Ms A told Dr B that she still did not fully understand the nature of the pseudoaneurysm and why it was not at risk of rupture. Ms A did not feel that she could go on holiday with her lack of understanding unresolved so she told Dr B she would seek further information from Dr D.

Dr B responded to Ms A by email later on the same day. At the outset, she said:

"I am sorry that you are frustrated and unhappy. I feel I have done everything in my power to be transparent, responsible, responsive and caring. I acknowledged immediately and openly to you that I had had a bleeder and that emergency suturing was required. I have sutured it quickly and stopped the bleed instantly. Complications do happen with surgery. Not a lot of people accept responsibility for their complications as openly and clearly as I do and many try to hide from the patients. I did not do this specifically, I have tried to work the open and helpful way."

Dr B continued to explain the follow-up that she and her nurses provided, emphasising that they have "wanted the best outcome for [Ms A]". She noted the need



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²³ November 2009

for fees for private services, and apologised that Ms A thought they were expensive. Dr B said she was glad Ms A was seeing Dr D, and noted:

"If he feels the pseudoaneurysm was caused by the emergency suturing, I will accept it and acknowledge it. However, if someone bleeds I have to stop the bleeding and as a surgeon I cannot guarantee a perfect result every time. I can only apologise and empathise with your frustrations."

In response to my investigation, Dr B explained that she raised the possibility that Ms A's pseudoaneurysm was caused before the surgery because she could not prove that it had been caused prior to or during surgery. Dr B remarked that she "[does] not like terrifying [her] patients especially without proof of cause ... I believed the stitch to have caused it and I did say so to the patient."

In her email of 17 August 2005, Dr B offered to ask Dr D to see Ms A urgently. Although she said she considered the gynaecological outcome of the surgery to have been satisfactory, Dr B also offered to provide a referral letter in the event that Ms A wanted to see another gynaecologist, or obtain a second opinion.

Vascular surgery to repair the pseudoaneurysm

On 18 August 2005, Ms A consulted Dr D regarding the pseudoaneurysm. After considering the options and information presented to her by Dr D, Ms A decided to proceed with the surgical repair option upon her return from holiday.

On 1 September 2005, Dr D carried out a surgical repair of a 3cm pseudoaneurysm on Ms A's left inferior epigastric artery. Dr D described this artery as a "moderately large vessel".

Ms A's recovery from her vascular surgery was uneventful. When Dr D reviewed her on 13 September 2005, she was well and felt more comfortable. On examination, Ms A's wound had healed well and there were no signs of recurrence. Dr D advised Dr B accordingly.

23 November 2009



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Code of Health and Disability Services Consumers' Rights

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

RIGHT 4

Right to Services of an Appropriate Standard

(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

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
 - •••
 - (e) Any other information required by legal, professional, ethical, and other relevant standards; ...

Other relevant standards

Medical Council of New Zealand statement, *Disclosure of harm 'Good medical practice'* (October 2004):

When a patient is harmed while receiving medical treatment the Medical Council expects that the patient's doctor will advise the patient of the facts of the harm in the interests of an open, honest and accountable professional relationship. Disclosure should be based on the patient's interests and information should not be withheld to protect the interests of the doctor.

25. Details about the nature of the harm, and any subsequent action including disclosure to the patient should be documented in the patient's record. The Council recommends the patient notes mention who was present, what was disclosed, the patient's reaction and any issues regarding continuity of care. If the harm occurred in secondary or tertiary care the patient's general practitioner must be informed.

Medical Council of New Zealand's statement, *The Maintenance and Retention of Patient Records* (August 2001):

a. Maintaining patient records

23 November 2009



- (a) Records must be legible and should contain all information that is relevant to the patient's care.¹⁴
- (b) Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory.

Opinion: Breach — Dr B

Open disclosure

Introduction

It is well understood that every surgical operation carries a risk of complication. Doctors have a duty of candour and patients have a right to full disclosure when something goes wrong during an operation. Right 6(1) of the Code affirms every consumer's right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. When a surgical complication occurs, the patient is entitled to open, truthful, and timely information about the complication, its effect and its significance. Open disclosure is not a single conversation but a process of ongoing communication. Communication should continue until the patient has all the information and support needed.¹⁵

As noted in case 02HDC14836, open disclosure is underpinned by respect for autonomy and promotes trust in the medical profession. Disclosure of adverse events also serves to minimise the potential harm of unknown conditions going untreated.¹⁶

A doctor's duty of open disclosure is affirmed by the Medical Council of New Zealand's statement on the Disclosure of harm 'Good medical practice' (October 2004).

There is no doubt that Dr B informed Ms A that a complication occurred during her gynaecological surgery. The issue is the adequacy of Dr B's disclosure to Ms A. Dr B claims that "a dispassionate regard for the evidence establishes that [I] did provide the patient with the information available to [me] and further advised the patient of [my] opinion and intended management as matters failed to resolve".

I do not accept that it was sufficient for Dr B simply to inform Ms A that "there had been a mishap during the operation". Guided by expert advice from consultant gynaecologist Dr Tal Jacobson, I consider that Dr B failed to provide Ms A with adequate information about the nature and cause of the unintended harm she suffered

¹⁶ General surgeon, Dr B, A Report by the Health and Disability Commissioner, case 02HDC14836 (24 March 2004).



¹⁴ The Medical Council's statement refers to Cole's Medical Practice in New Zealand for further guidance on record management.

Health and Disability Commissioner, Guidance on Open Disclosure Policies, 22 March 2007.

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as a result of the complication during her surgery. The reasons for my opinion are outlined below.

Information about unintended harm

A critical aspect of open disclosure in the event of a surgical complication is clear, accurate, and balanced information about the nature of any actual or potential unintended harm.

Dr B stated that during or immediately after Ms A's operation, "there was no reason to expect the puncture and repair would give rise to any future difficulties". She acknowledged that pseudoaneurysms are a well-recognised complication of surgery, arterial puncture and trauma. Dr B said "pseudoaneurysm of the inferior epigastric artery is a recognised complication but is very rare, the literature indicates only eight cases had ever been reported until 2002 and [she has] located one subsequent report".¹⁷ She also claimed that vascular surgeon Dr D "himself has never experienced this complication".

I do not criticise Dr B for failing to predict the left inferior epigastric artery pseudoaneurysm at the time of Ms A's complicated laparoscopy, or in the early postoperative period. My focus is on the adequacy of Dr B's disclosure of what was apparent at the time.

Blood vessel injury

Dr B recorded what happened in her operation note. I accept that the primary purpose of operation notes is to accurately record the details of an operation and inform future clinical management. However, in this case, it is clear that Dr B also used her operation note to communicate information to Ms A directly.

In the operation note, Dr B recorded that her left iliac fossa port went through an "arteriole". Dr B explained that this record reflects her understanding of the nature of the complication at the time. She thought the injured vessel was an arteriole, rather than an artery such as the inferior epigastric artery, because the blood flow was not consistent with damage to an artery. Dr B stated that if the blood oozes the injured vessel is a capillary, and if the bleeding pumps with heartbeats and fills it is likely to be an artery. She said the characteristics of the bleeding in this case were in between what is usual for a capillary and an artery; hence she thought the injured vessel was an arteriole.

Dr B said that her genuine belief that the injured vessel was an arteriole is supported by her obtaining haemostasis without assistance. She stated that if there had been a major bleed apparently involving an artery, she would certainly have had more



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¹⁷ Dr B cited the following article: Rege SA, Hanchate V, Rohondia O. Pseudo-aneurysm of the inferior epigastric artery: a rare complication of abdominal wall suturing. *The Internet Journal of Surgery* 2005: Vol 6, No 1. It appears she is referring to the literature review outlined in: Werner M, Bernheim J and others. *Pseudoaneurysm of the inferior epigastric artery: a rare complication of Tenckhoff catheter removal.* Nephrol Dial Transport (1999) 14: 1297–1299.

²³ November 2009

difficulty controlling the bleeding and would have been very likely to ask a general surgeon to come to theatre.

Dr Jacobson provided advice on the nature of arterioles and the inferior epigastric artery. He advised that the diameter of an arteriole is 10–50 micrometres (0.1–0.5mm) — less than a single human hair, and arterioles are only a few millimetres in length. Dr Jacobson explained that an arteriole cannot be clearly distinguished with the naked eye or with the laparoscope. He advised that the "200mls+" bleeding described by Dr B in her operation note would be considered to be a significant amount of bleeding during laparoscopic surgery. However, very small vessels are unlikely to bleed significantly in this scenario. Dr Jacobson advised that arterioles would not usually be a target of surgical intervention because they are simply too small to warrant or allow it. He is not aware of any arterioles that are specifically described in the gynaecological surgical literature or that have clinical relevance in gynaecological surgery.

Dr Jacobson advised that in contrast to arterioles, the inferior epigastric artery is well described and well known by laparoscopic gynaecological surgeons as a vessel to be avoided in the location of Ms A's surgery. He explained that an artery such as the inferior epigastric artery is easily visually identifiable with a diameter of approximately 250 to 350 micrometres (2.5–3.5mm). Dr Jacobson advised that if the inferior epigastric artery is injured, it can cause a significant amount of bleeding and is amenable to surgical intervention such as suturing.

Dr Jacobson does not believe a reasonable surgeon would require the benefit of hindsight to consider injury of the inferior epigastric artery as the most likely diagnosis both during and after Ms A's operation.

Dr Jacobson further stated:

"If [Dr B] genuinely thought that the vessel she was dealing with at the time of surgery was an arteriole rather than an artery (and, in particular, the well known inferior epigastric artery), then I believe that this is a significant concern. It suggests a fundamental misunderstanding of basic anatomy."

I am satisfied that as a consultant gynaecologist, Dr B has a comprehensive knowledge of human anatomy, particularly in the region of the female reproductive system. Guided by Dr Jacobson's advice about the anatomy of arterioles, I do not accept that Dr B thought the injured vessel was an arteriole.

Dr Jacobson commented on Dr B's description of the injured vessel as an "arteriole" in her operation note. He advised:

"I would expect that the diagnosis of injury to the inferior epigastric artery would have been strongly considered as the primary diagnosis and documented by [Dr B] as such rather than a description of an 'arteriole' that suggests an innominate and very small vessel. I would consider this to be a moderate departure from accepted practice and would be viewed by her peers with moderate disapproval."



Dr B's gynaecology expert, Dr John Tait, commented that "perhaps the use of the term arteriole is unfortunate", but this did not affect subsequent clinical management, or in his view, cause a delay in diagnosis of the pseudoaneurysm. I acknowledge Dr Tait's comments, but note that the key issue relates to Dr B's candour, not the clinical consequences of her lack of candour.

I accept Dr Jacobson's advice that it was inappropriate for Dr B to describe the injured blood vessel as an "arteriole". In the face of objective anatomical information, Dr B's use of the term defied logic and was inappropriate.

By describing the injured vessel as an arteriole, Dr B failed to provide Ms A (or any clinicians relying on her operation note in the future) with clear, accurate, and balanced information about the characteristics of the injured blood vessel. As a result, Dr B did not provide adequate information about the nature of the unintended harm.

Ms A's ongoing symptoms

When Ms A presented to Dr B for her second follow-up appointment on 23 June 2005, Dr B noted that Ms A had some postoperative bruising, muscle tenderness, and some residual pubic tubercular pain. Dr B suggested that this could be mild osteitis or a mild ligament pull. Dr B stated that the reason she thought the ongoing symptoms may have been mild osteitis or a mild ligament pull was that Ms A's earlier symptoms had largely resolved. Dr Jacobson advised:

"Although neither of these suggested diagnoses [mild osteitis or a mild ligament pull] is impossible, it would seem much more likely that the signs and symptoms are related to the original vessel injury and the subsequent complication that turned out to be a pseudo-aneurysm. I would expect that this should have been the primary working diagnosis (ie, the pain was related to the vessel injury) with these other rare diagnoses as secondary possibilities. I would consider that this diagnostic oversight is a moderate departure from accepted practice and would be viewed by her peers with moderate disapproval."

Even Dr B's expert, vascular and endovascular surgeon Dr Richard Evans, commented:

"There is a possibility that the patient's postoperative pain was more musculoskeletal in origin such as a ligament sprain or mild osteitis. However given the sequence of events it is more likely that the patient's left lower quadrant pain was caused by the surgical insertion of a trocar with subsequent arterial damage and the events that flowed from this."

Similarly, Dr Tait advised that "[w]ith regard to the suggestion of mild osteitis or a mild ligament pull, the symptom would most likely ... be associated with damage to the blood vessel".

Dr B submitted that "without the benefit of hindsight, it is hard to be critical of [me] for not making both the assumptions that there was a pseudoaneurysm and that the ultrasound scan had missed the problem".

²³ November 2009



I am not criticising Dr B for failing to diagnose the pseudoaneurysm at this time, but for her failure to be open with Ms A about the most likely cause of her ongoing symptoms — the vessel injury during surgery. Dr Jacobson, Dr Tait, and Dr Evans all agree that at the time, the vessel injury during surgery was the more likely cause of Ms A's ongoing symptoms. I accept Dr Jacobson's advice that in the circumstances, it was inappropriate for Dr B to suggest that Ms A's ongoing symptoms were attributable to rare diagnoses rather than the more likely cause.

By failing to inform Ms A that her ongoing symptoms were likely to be related to the vessel injury during surgery, Dr B failed to provide Ms A with sufficient information about the cause of her ongoing symptoms. This potentially led to unnecessary consultations with other healthcare providers, and a delay in treatment of the underlying condition.

Ms A's pseudoaneurysm

On 16 August 2005, Dr B referred Ms A to vascular surgeon Dr D by email and she sent a copy of her email to Ms A at the time. In her referral email, Dr B introduced Ms A and her clinical condition as follows:

"Please could you see [Ms A] for advice and assessment. She has been found on a recent [ultrasound scan] to have a pseudo-aneurysm possibly in the region of the superior epigastric artery or one of its smaller branches. I am not sure if this anatomy predates the operation or is as a result of the emergency stitch required to stop the bleeding."

Ms A was particularly unhappy about Dr B's suggestion that her pseudoaneurysm could have been present prior to the surgery. In an email the next day, Ms A told Dr B that the possibility of a pre-existing pseudoaneurysm seemed "highly unlikely", and she appeared to be "avoiding responsibility" by making this suggestion. Dr B replied by assuring Ms A that she was not avoiding responsibility. She said that "if [Dr D felt] the pseudoaneurysm was caused by the emergency suturing, [she would] accept it and acknowledge it".

In response to my investigation, Dr B explained that she raised the possibility that Ms A's pseudoaneurysm was caused prior to the surgery because she could not prove that it had been caused prior to or during surgery. Dr B remarked that she "[does] not like terrifying [her] patients especially without proof of cause ... I believed the stitch to have caused it and I did say so to the patient".

Dr B claims that at no time did she herself suggest that the pseudoaneurysm was more likely to be pre-existing and spontaneous than as a result of the surgical complication. However, I share Ms A's and Dr Jacobson's concern that by the order of Dr B's words, she suggested that a spontaneous pseudoaneurysm was equally or more likely than a pseudoaneurysm secondary to traumatic injury. Dr Jacobson said that although it is not impossible that Ms A's pseudoaneurysm was pre-existing, "it is extremely unlikely, and yet it is given equal or greater likelihood compared to being a consequence of the surgical complication". He advised:

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"A pseudo-aneurysm is usually due to traumatic injury to a vessel. Although they can occur spontaneously, in this case the vessel trauma has been clearly documented at the time of surgery. It is very unlikely to have predated the surgery. I would expect that a complication resulting from damage and repair to this vessel would be considered to be the most likely cause of the patient's symptoms in the post operative period. Although this use of language and terminology had no clinical impact on the care given, I would consider that this is a moderate departure from accepted practice and would be viewed by her peers with moderate disapproval."

Dr Evans agreed that "there is a very low likelihood that the false aneurysm was present preoperatively ... in all likelihood it was caused by the direct trocar injury to the artery".

In her response, Dr B discussed uncertainty and the role of relative likelihood in medical practice. She said:

"Relative likelihoods form part of clinical impression and differential diagnosis. Doctors are taught that they should always have differential diagnoses to avoid a fixed and unalterable system of thought which is not considered mature or safe. Certainty is obtained in such scenarios only with hindsight."

I agree that doctors should always consider differential diagnoses and be open with patients about the level of diagnostic uncertainty. However, any primary or differential diagnosis considered and communicated to a patient must be based on a reasonable assessment of likelihood in the circumstances.

I accept Dr Jacobson's advice that it was inappropriate for Dr B to suggest that Ms A's pseudoaneurysm was equally or more likely to be pre-existing and spontaneous, rather than a consequence of the surgical complication. By making this suggestion in correspondence copied to Ms A and contained on her clinical record, Dr B failed to provide Ms A with the clear, accurate, and balanced information about the cause of her pseudoaneurysm that she was entitled to under Right 6(1) of the Code.

Risk of rupture

In her email referral to Dr D of 16 August 2005, copied to Ms A, Dr B said:

"I have indicated to her based on our chat today regarding the [ultrasound scan] report that there are a few options, conservative, exploratory ligation and thrombotic. I have also indicated that it is probably not an acute issue that needs to be worried about too much and immediately."

Dr B contacted vascular and general surgeon Dr D on receipt of the radiology report to obtain his opinion on the pseudoaneurysm finding. Although there is no direct written record of what was said during their conversation, Dr B recalls that Dr D informed her that pseudoaneurysms of this kind are very rare. She recalls his advice that Ms A's pseudoaneurysm was not at immediate risk of rupture because it was likely to be small, the area was well compressed in tight compacted tissue, there was



²³ November 2009

already a suture around the artery, and it appeared not to be leaking. Dr B states that Dr D advised her to tell Ms A that her pseudoaneurysm was unlikely to rupture.

Dr Jacobson commented on Dr B's assurance to Ms A that her pseudoaneurysm was "probably not an acute issue that needs to be worried about too much and immediately". He advised:

"A pseudo-aneurysm is a leakage of arterial blood from an artery into the surrounding tissue, through the site of injury, with a persistent communication between the originating artery and the resultant adjacent cavity. It can potentially be very dangerous if the surrounding tissue that is acting as a replacement for the artery wall subsequently gives way and significant blood loss can occur into large tissue spaces. I think that it would have been more appropriate to advise Ms A that there was a risk of rupture, rather than reassure her that it was 'probably not an acute issue that needs to be worried about too much'. The precise interpretation of the severity and risk of complications of a pseudo-aneurysm of this kind are open to individual interpretation and therefore I consider this to be a reasonable standard of care."

As noted by Dr Jacobson, it would have been preferable for Ms A to be warned of the risk of rupture. However, I accept that Dr B acted reasonably in conveying the specialist opinion she had obtained from Dr D.

An impression of "clinical denial"

In summing up his opinion on the care provided in this case, Dr Jacobson noted the general sense of "clinical denial" throughout Dr B's medical notes. By this he meant that "the obvious or most likely diagnoses are not considered or specifically documented because they may imply some element of failure by the clinician". Dr Jacobson cited in particular Dr B's reference to the injured vessel as an "arteriole", and her suggestion that Ms A's pseudoaneurysm was equally or more likely to be pre-existing and spontaneous, rather than a consequence of the surgical complication.

I share Dr Jacobson's impression of clinical denial. In legal terms it might be called "*suppressio veri*" — suppression of the truth. A surgeon's duty of open disclosure requires him or her to be open and honest about complications that occur during surgery, and not to obfuscate or obscure the known or suspected clinical picture. The Medical Council's statement on the disclosure of harm is clear that "disclosure should be based on the patient's interests and information should not be withheld to protect the interests of the doctor". In my view, Dr B was less than frank to protect her own interests, to the potential detriment of Ms A and her future clinical care.

I note Dr B's statement (in her email of 17 August 2005 to Ms A) that she had "done everything in [her] power to be transparent, responsible, responsive and caring". Using the right words is no substitute for doing the right thing.¹⁸ Acknowledging that an adverse event has occurred can be hard, and facing up to an injured patient openly

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¹⁸ See Bismark M and Paterson R. "Doing the right thing" after an adverse event. *NZMJ* 2005; 188:1219, available online at http://www.nzma.org.nz/journal/118-1219/1593/.

and honestly can be even harder. But the alternative of obfuscation or withholding information is worse, for patients, their families, and their healthcare providers.¹⁹

Conclusion

Overall, I conclude that by:

- (1) describing Ms A's injured vessel as an "arteriole" in the operation note;
- (2) failing to inform Ms A that her ongoing pain on 23 June 2005 was likely to be related to the vessel injury during surgery; and
- (3) suggesting that Ms A's pseudo-aneurysm was equally or more likely to be preexisting and spontaneous, rather than a consequence of the surgical complication,

Dr B did not provide Ms A with the information that a reasonable patient, in her circumstances, would expect to receive. Dr B was required to provide this information according to her duty of open disclosure, and the professional and ethical standard set out in the Medical Council's statement on the disclosure of harm. By failing to provide this information to Ms A, Dr B breached her duty of open disclosure, and Right 6(1) of the Code.

Documentation

Under Right 4(2) of the Code, Ms A was entitled to services that complied with professional standards. The medical profession maintains clear professional standards regarding documentation of medical services.

Appropriate documentation is essential for coordination between providers, and to ensure consistency and quality of care. According to the Medical Council's statement on *The Maintenance and Retention of Patient Records* (August 2001), "Records must be legible and should contain all information that is relevant to the patient's care." The Medical Council further states:

"Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory."

The Medical Council's statement on the disclosure of harm is also clear that doctors have a professional and ethical duty to document the details of any harm experienced by a patient while receiving medical treatment in the patient's records.

Dr Jacobson commented on the standard of Dr B's documentation, particularly in relation to the operation note dated 10 May 2005. He observed that the operation note



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¹⁹ Lamb R. Open disclosure: the only approach to medical error. *Quality and Safety in Health Care*. 2004;13:3–5, available online at: [http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1758054& blobtype=pdf].

²³ November 2009

contained no description of the "hysteroscopic findings, the method of hysteroscopy, the type of fluid distension used, the method of endometrial ablation, [or] whether endometrial curettings were taken or chipping sent for histology". Dr Jacobson advised that they should be a standard part of the operation record, and that their omission was a moderate departure from accepted practice. He considered it unacceptable for Dr B to include minimal detail of her technique, given that this was a "complicated" procedure. The standard of documentation should be sufficient to allow another practitioner to understand what happened and what was done, and in Dr Jacobson's view, Dr B's documentation failed that standard. He advised that describing the injured vessel as an "arteriole" in the operation note was also inadequate documentation.

Dr B obtained Dr Tait's advice on the standard of her documentation in this case. He noted there was "no documentation regarding the endometrial ablation", and "perhaps the use of the term arteriole [was] unfortunate", but considered that overall Dr B had documented the laparoscopic procedure adequately. In his opinion, Dr B's documentation was sufficient to allow another practitioner to understand what happened and what was done.

I acknowledge Dr Tait's advice but do not agree with his overall conclusion. I do not accept that Dr B's minimal documentation of her surgical technique in a complicated procedure, or her use of the term "arteriole", was appropriate or adequate in the circumstances. In preferring Dr Jacobson's advice on this issue, I note that he is an independent expert advisor who has been provided with all the relevant information.

Guided by Dr Jacobson's advice, I consider that Dr B failed to adequately record in her operation note the details of the operation and the nature of the harm experienced by Ms A. This was a departure from professional and ethical standards for documentation and a breach of Right 4(2) of the Code.

Opinion: No breach — Dr B

Follow-up care

Ms A was concerned that Dr B did not provide her with appropriate follow-up care after her gynaecological surgery. Dr Jacobson advised:

"There is no specific standard of follow-up and I consider the follow-up time to be acceptable practice but in my view it would have been prudent to arrange an earlier follow-up. Earlier and more intensive investigation may have resulted in an earlier diagnosis of the pseudo-aneurysm.

• • •



If the diagnosis of a pseudo-aneurysm or other complication of the original vascular injury had been considered then this could potentially have led to the diagnosis being made earlier. Nevertheless the diagnosis of pseudo-aneurysm is not common and it is understandable that there may have been delay in making the diagnosis."

I conclude that Dr B's follow-up care of Ms A was adequate and she did not breach the Code in this regard.

Recommendations

I recommend that Dr B:

- Apologise to Ms A for her breaches of the Code. This apology is to be sent to HDC and will be forwarded to Ms A.
- Review her practice in light of this report and the comments of my expert.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand.
- A copy of this report, with details identifying the parties removed except the name of Dr B, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.
- A copy of this report with details identifying the parties removed, except my expert advisor, Dr Tal Jacobson, and Dr B's experts, Dr John Tait and Dr Richard Evans, will be placed on the HDC website, <u>www.hdc.org.nz</u>, for educational purposes.



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Appendix 1: Independent advice — gynaecologist Dr Tal Jacobson

The following expert advice was obtained from consultant obstetrician and gynaecologist Dr Tal Jacobson.

"In providing this advice, I acknowledge that I have read and agree to follow the Guidelines for Independent Advisors (Appendix H) effective date 5 March 2007.

My name is Dr Tal Jacobson and my qualifications are MA (Cantab) MBBS (Lond) MRCOG FRANZCOG. I am a Senior Lecturer in Obstetrics and Gynaecology at the University of Auckland and Consultant in Obstetrics and Gynaecology at Counties Manukau District Health Board. I have specific experience in Minimal Access (Keyhole) Surgery. During my training, I completed a two year Fellowship in Minimal Access Surgery at Bart's and the Royal London Hospitals, London, UK. I am the lead clinician for Gynaecological Minimal Access Surgery at Counties Manukau DHB. I specialise in the treatment of endometriosis, pelvic pain, menstrual disorders and infertility. I run regular training courses to teach various aspects of minimal access surgery to both junior and senior gynaecologists. My research interests are focussed on the safety and ergonomics of minimal access surgery as well as the treatment of endometriosis.

I have been asked by the Commissioner to:

- a) advise whether I consider [Dr B's] care was of a reasonable standard.
- b) consider if any aspect of this care departed from accepted practice and indicate how significant the departure is.

[Dr Jacobson listed the supporting documents that HDC provided to him for the purposes of his expert advice. This list has been removed for the sake of brevity.]

Brief summary of events:

On 10th May 2005, [Ms A] underwent hysteroscopy, endometrial resection and laparoscopic sterilisation. This surgery was performed by [Dr B] During the laparoscopy, significant bleeding was identified from the left sided port. This was controlled by inserting two further ports and placing two sutures laparoscopically. Fluid was aspirated from a small cyst on the left ovary and then the tubal ligation was completed with two Filshie clips applied to each tube. [Ms A] was discharged from hospital the following day. Following the surgery, she developed pain in the left iliac fossa. An initial ultrasound scan suggested a haematoma. The pain persisted and a further ultrasound on 15th August 2005 diagnosed a left iliac fossa pseudo-aneurysm. On 1 September 2005 she underwent surgery by a vascular surgeon. A pseudo-aneurysm of the left inferior epigastric artery was identified and repaired.

In the following report will address specific areas of the case and provide my opinion on the standard of care:-

- 1 Consent
- 1.1 Specific complications that may occur during surgery are not stated on the signed consent form but they are specified on the information sheets supplied by [Dr B] to [Ms A]. This is perfectly acceptable practice assuming that the information sheets are actually read by, or discussed with, the patient. One advantage of adding them to the consent form is that the consent form is actually signed by the patient indicating that they have been read and understood. Overall, [Dr B's] patient information handouts are extremely thorough and comprehensive and would be a valuable resource for patients both before and after their surgery.
- 1 2 The risk of failure of contraception is documented in [Dr B's] tubal ligation consent form as 1 in 5000. This is probably a little bit optimistic. Most authorities quote a failure rate of 1 in 200 to 1 in 500 based on well known publications.²⁰ [Dr B] does qualify her comment slightly saying that this does not include the failures associated with surgeon error but patients are interested in the overall risk rather than the risk of specific causes of failure. The exact failure rate is debateable and therefore the most important consideration is that a failure rate has been discussed. I would therefore consider this to be a reasonable standard of care and not a departure from accepted practice.
- 2 In the operation note dated 10 May 2005, the operation is described as:

'laparoscopy, Filshie Clip sterilization, Hysteroscopic endometrial resection'.

- 2.1 There is no description in the formal operation note of the hysteroscopic findings, the method of hysteroscopy, the type of fluid distension used, the method of endometrial ablation, whether endometrial curettings were taken or chippings sent for histology. These should be a standard part of the operation record.
- 2.2 The photographs document the resection/ablation procedure and there is a histology report confirming that it was undertaken.
- 2.3 [Dr B] states that there was a problem with her electronic note keeping system which meant that these notes were lost.
- 2.4 The failure to formally document this part of the operation in the operation note is likely to be an oversight and/or record keeping problem and although it is a moderate departure from accepted practice it is of little

²⁰ Kovacs GT, Krins AJ. Female sterilisations with Filshie clips: What is the risk of failure? A retrospective survey of 30 000 applications. The Journal of Family Planning and Reproductive Health Care 2002; 28(1):34. Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization:

Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings for the U.S. Collaborative Review of Sterilization. American Journal Obstetrics & Gynaecology, April 1996, 174:1161 (CREST Study).

consequence or significance but the lack of documentation would be viewed by her peers with mild to moderate disapproval.

- 3 In the operation record dated 10 May 2005, [Dr B] describes the procedure as 'complicated laparoscopy'.
- 3.1 There is limited description of the method of establishing the pneumoperitoneum and the laparoscopic technique. The port placements for the two extra ports are not documented. A 10mm midline port for the clip applicator is documented but it does not appear to be necessary if two further 5mm ports had already been placed and the original intention was to place the Filshie clips via a 5mm left lateral port.
- 3.2 If a procedure is straightforward it may be considered acceptable to document it as 'standard technique' if the practitioner has a standard technique that they always use. If a procedure is described as 'complicated', I would expect the standard of documentation to be sufficient to allow another practitioner to understand what has happened and what has been done. I do not consider the documentation to be adequate in this case. This is a moderate departure from accepted practice and would be viewed by her peers with minor disapproval.
- 3.3 The vessel that was injured is described in the operation note as an 'arteriole'. I would expect that the diagnosis of injury to the inferior epigastric artery would have been strongly considered as the primary diagnosis and documented by [Dr B] as such rather than a description of an 'arteriole' that suggests an innominate and very small vessel. I would consider this to be a moderate departure from accepted practice and would be viewed by her peers with moderate disapproval.
- 3.4 If injury occurs to the inferior epigastric artery and this is recognised at the time of surgery, there are a number of established ways of controlling the bleeding. It is reasonable to place sutures laparoscopically. Another option is to place large sutures through the skin, above and below the site of injury to the inferior epigastric artery. Using a balloon catheter and radiological embolisation are also recognised methods.
- 3.5 Although the active bleeding was controlled by laparoscopic suturing, the figure-of-8 sutures did not actually ligate the vessel above and below the injury site therefore the pseudo-aneurysm developed and persisted. I do not consider this to be substandard care as, at the time of surgery, creating haemostasis (stopping the bleeding) would be sufficient.
- 4 In the operation record dated 10 May 2005 it states 'Filshie clips X 2 FOR EACH FALLOPIAN TUBE'
- 4.1 It is standard practice to apply one Filshie clip to each tube. A second may be applied if the initial clip application is loose or does not appear to be

23 November 2009



right across the tube. Routinely applying two clips to each tube does not improve the success rate of the operation but can increase the complication rate as well as the cost.

- 4.2 I understand from her consent form that [Dr B] routinely applies two clips to the tubes. Although this is less commonly performed it is a reasonable standard of practice.
- 5 [Dr B] reviewed [Ms A] four weeks after the surgery on 9 June 2005.
- 5.1 A significant complication had occurred and [Ms A] subsequently expressed concern to [Dr B's] nurse on at least two separate occasions. This is a significant area of complaint from the patient. There is no specific standard of follow-up and I consider the follow-up time to be acceptable practice but in my view it would have been prudent to arrange an earlier follow-up. Earlier and more intensive investigation may have resulted in an earlier diagnosis of the pseudo-aneurysm.
- 6 [Dr B] performed an ultrasound scan which revealed a 2cm diameter haematoma at the site of the left port vessel injury.
- 6.1 [Dr B] has said she has specific ultrasound training and experience including the use of Doppler and colour flow. She did not use these modalities when performing the follow-up scans. If the diagnosis of a pseudo-aneurysm or other complication of the original vascular injury had been considered then this could potentially have led to the diagnosis being made earlier. Nevertheless the diagnosis of pseudo-aneurysm is not common and it is understandable that there may have been delay in making the diagnosis.
- 7 In the letter dated 23 June 2005 to the GP [Dr C], [Dr B] acknowledges that there is post operative bruising and muscle tenderness but attributes ongoing pain to '? mild osteitis, ? mild pull at insertion point of round ligament'.
- 7.1 Although neither of these suggested diagnoses is impossible, it would seem much more likely that the signs and symptoms are related to the original vessel injury and the subsequent complication that turned out to be a pseudo-aneurysm. I would expect that this should have been the primary working diagnosis (ie, the pain was related to the vessel injury) with these other rare diagnoses as secondary possibilities. I would consider that this diagnostic oversight is a moderate departure from accepted practice and would be viewed by her peers with moderate disapproval.
- 8 In the letter dated 17th August 2005 from [Dr B] to [Dr D], she states that she is not sure if the pseudo-aneurysm 'predates the operation or is as a result of the emergency stitch required to stop the bleeding'.



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²³ November 2009

- 8.1 I am concerned that [Dr B] would suggest by the order of her words that a <u>spontaneous</u> pseudo-aneurysm is equally or more likely to be the cause than <u>secondary</u> to traumatic injury. A pseudo-aneurysm is usually due to traumatic injury to a vessel. Although they can occur spontaneously, in this case the vessel trauma has been clearly documented at the time of surgery. It is very unlikely to have predated the surgery. I would expect that a complication resulting from damage and repair to this vessel would be considered to be the most likely cause of the patient's symptoms in the post operative period. Although this use of language and terminology had no clinical impact on the care given, I would consider that this is a moderate departure from accepted practice and would be viewed by her peers with moderate disapproval.
- 9 She also stated that it was 'probably not an acute issue that needs to be worried about too much and immediately'.
- 9.1 A pseudo-aneurysm is a leakage of arterial blood from an artery into the surrounding tissue, through the site of injury, with a persistent communication between the originating artery and the resultant adjacent cavity. It can potentially be very dangerous if the surrounding tissue that is acting as a replacement for the artery wall subsequently gives way and significant blood loss can occur into large tissue spaces. I think that it would have been more appropriate to advise [Ms A] that there was a risk of rupture, rather than reassure her that it was 'probably not an acute issue that needs to be worried about too much'. The precise interpretation of the severity and risk of complications of a pseudo-aneurysm of this kind are open to individual interpretation and therefore I consider this to be a reasonable standard of care.

Summary of opinion:

Complications such as injuring the inferior epigastric artery can occur with any surgical procedure. In this specific case the initial complication was recognised and managed. It was appropriate initial management but the documentation is poor. There was delay with the subsequent diagnosis of the pseudo-aneurysm but this is a rare diagnosis and perhaps understandable in this context.

There is a general feeling from the notes of 'clinical denial'. That is, that the obvious or most likely diagnoses are not considered or specifically documented because they may imply some element of failure by the clinician. In particular:

- 1) The inferior epigastric artery is initially referred to as an 'arteriole' when it is quite clear that the most likely vessel to be involved was the inferior epigastric artery.
- 2) It is suggested by [Dr B] in correspondence with the vascular surgeon (letter to [Dr D] dated 16 August 2005) that the pseudo-aneurysm could have been preexisting. Although this is not impossible, it is extremely unlikely, and yet it is



given equal or greater likelihood compared to being a consequence of the surgical complication.

Overall, I think that there are areas where the care provided did not meet a reasonable standard with variable degrees of departure from accepted practice."

Further expert advice

I sought further expert advice from Dr Jacobson in light of the clinical issues raised in [Dr B's] response to my provisional opinion. His advice follows.

"Thank you for your email dated 25 August 2009 requesting a further opinion on this matter.

In providing this further advice I have read:

1) the Commissioner's provisional opinion 08/08586

2) [Dr B's] response to the Commissioner's provisional opinion

I have been asked by the Commissioner to provide further comment on the services provided by [Dr B] in light of the specific clinical matters raised in her response:

Operation Note

An operation note is written primarily for the surgeon to keep a detailed record of the findings and events. This will allow them to review and continue ongoing management as well as to allow them to provide information to the patient at subsequent meetings.

It also serves to allow other health professionals to interpret the events. Although it may be copied to the patient, it is generally not written to inform the patient directly as it usually contains technical language that may require interpretation and explanation.

In general, the operation note is certainly used by the surgeon or any other health practitioner, such as the GP or another surgeon, to inform the patient at any subsequent meetings, of the events that occurred during the surgery.

Arteriole

In gynaecological surgery it would be very unusual to refer to a vessel that is operated on as an arteriole. They are simply too small to warrant or allow individual surgical intervention in this context.

The inferior epigastric artery is well described and well known by laparoscopic gynaecological surgeons as a vessel to be avoided in this location. Small unnamed vessels are often encountered during surgery and may require intervention to control bleeding from them but I am not aware of any arterioles



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²³ November 2009

that are specifically described in the gynaecological surgical literature or that have clinical relevance in gynaecological surgery.

An artery such as the inferior epigastric artery has a diameter of approximately 250 to 350 micrometers (2.5-3.5 mm). This is easily visually identifiable. If injured, it can cause a significant amount of bleeding. It is amenable to surgical intervention such as suturing.

At laparoscopic surgery '200mls+' would be considered to be a significant amount of bleeding. If much greater bleeding than this occurred then it may be difficult to obtain an adequate view laparoscopically due to the amount of blood. Conversion to laparotomy (open operation) may then be required.

An arteriole has a diameter of 10-50 micrometres and is only a few millimetres long. To put that in context, a single human hair has a diameter of approximately 80-100 micrometres. A vascular capillary has a diameter of 5-10 micrometres. Very small vessels are not likely to bleed significantly in this context. An arteriole can not be clearly distinguished with the naked eye or with the laparoscope and would not usually be a target of surgical intervention.

In general, if the diagnosis is not clear then a differential diagnosis should be considered with the most likely and/or the most serious being given priority for investigation or management.

Subsequent diagnosis and treatment confirmed that the vessel was indeed the inferior epigastric artery. I do not think that hindsight is required to consider this as the most likely diagnosis both intra-operatively and post-operatively.

The fact that in hindsight there was an incorrect diagnosis is not in itself the issue. It is that by far the most likely diagnosis was not considered at the time and that the vessel was described as an arteriole which would imply a small and irrelevant injury.

If [Dr B] genuinely thought that the vessel she was dealing at the time of surgery was an arteriole rather than an artery (and, in particular, the well known inferior epigastric artery), then I believe that this is a significant concern. It suggests a fundamental misunderstanding of basic anatomy.

[Dr B] dealt with the complication appropriately at the time of surgery but should have considered injury to the inferior epigastric artery as the most likely diagnosis."

23 November 2009



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