Vascular surgery in Victorian public hospitals 2005–06

Report to the public

Department of Human Services

A Victorian Government initiative

Victoria The Place To Be

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Introduction

‘Quality is not an act. It is a habit.’

Aristotle 384BC-322BC, Greek philosopher and scientist

The Melbourne Vascular Surgical Association (MVSA) was formed over ten years ago by the vascular surgeons working in Melbourne. The Association currently has a membership of approximately 35 active surgeons. As a result, all the relevant Melbourne public hospitals as well as 2 large rural hospitals are represented. A large amount of privately performed vascular surgery activity is also contributed by members.

The MVSA commenced an independent audit of its members’ operative results in 1999. In order to manage the increasing volume of data being collected a co-operative arrangement exists between the MVSA, the Victorian Department of Human Services Quality and Safety Branch, the Royal Australasian College of Surgeons and the Australian and New Zealand Society for Vascular Surgery. This cooperative has reviewed Victorian public hospital vascular surgery outcome results since 2003.

Five areas of vascular surgery were determined to be appropriate for audit in order to assess performance of Victoria’s vascular surgical units. This has been done under the auspices of the Melbourne Vascular Surgery Quality Initiative (MVSQI).

The areas of vascular surgery assessed are:

- Mortality, stroke rate and incidence of cranial nerve damage after carotid endarterectomy
- Death rate after repair of infra-renal aortic aneurysm (elective and ruptured)
- Occlusion rate after infra-inguinal bypass (for claudication and for tissue loss)
- Amputation rate after infra-inguinal bypass
- Length of hospital stay for each of these 3 groups

These terms are explained in more detail later in the report.

This report includes data for the period 1 July 2005 to 30 June 2006. Cumulative data covering several years is also included for comparative purposes. This is necessary since some operations are performed infrequently or the incidence of complications is very low. In such cases, it is only by summing the data over several years that adequate numbers can be accrued to permit meaningful analysis.

The following thirteen public hospitals participate in the audit process.

Table 1: Participating public hospitals

Hospital	Surgeon in charge of data collection
Alfred Hospital	Mr Geoff Cox
Austin Hospital	Mr Gary Fell
Ballarat Hospital	Mr Michael Condous
Box Hill Hospital	Mr Barry Beiles
Dandenong Hospital	Mr Roger Bell
Frankston Hospital	Mr George Somjen
Geelong Hospital	Mr David McClure
Monash Medical Centre	Mr Roger Bell
Northern Hospital	Mr Bernard Allard
Royal Melbourne Hospital	Mr Bernard Allard
St. Vincent's Hospital	Mr Mark Westcott
Western Hospital	Mr Barry Beiles
Williamstown Hospital	Mr Gary Frydman

MVSQI Steering Committee members

Representing the Melbourne Vascular Surgery Association

- Mr Barry Beiles
- Mr Andrew Roberts
- Mr Campbell Miles
- Mr Geoffrey Cox

Representing the Department of Human Services

- Mr Steven McConchie

Aggregate results

The data collected since 1999 clearly shows that vascular surgery in Victorian hospitals is safe in comparison with international and national benchmarks. Data is collected in both private and public hospitals, but data analysis is confined to the public hospitals. Privately submitted data was also included in the numbers for demographic purposes to assess Victorian patterns, but were not included in the data analysis later in this report.

Across the group of surgery types reported here the majority of patients are male (75%) with a mean age of approximately 74 years.

Table 2: Vascular surgery demographic data

Surgery type	Male	%	Female	%	Total operations
Aortic aneurysm (Elective)	223	85.4	38	14.5	**261**
Aortic aneurysm (Ruptured)	62	83.8	12	16.2	**74**
Carotid endarterectomy	277	72.1	107	27.9	**384**
Infra-inguinal bypass	311	70.7	129	29.3	**440**
Total	873	75.3	286	24.7	**1159**

Length of stay for the procedures ranges from 3-12 days according to the procedure and its complexity.

Table 3: Length of stay (median)

Surgery type	Days
Carotid endarterectomy	3
Infra-inguinal bypass	10
Aortic aneurysm (Elective)	7
Aortic aneurysm (Ruptured)	12

The vascular surgery group risk factor profile for the 2005-06 data set is significant. A very high proportion of subjects had high blood pressure (78.6%), smoking history (78%), high cholesterol (68.9%), heart disease (53%) and diabetes (31.7%). Moreover, 5.3% of patients had impaired kidney function while 2% of patients were on dialysis. Despite the incidence of several high risk factors the adverse outcome event rate was very low.

Mortality

The risk profiles vary considerably between patients. Emergency procedures, high-risk patients that suffer from diabetes, high cholesterol, high blood pressure, are smokers and over 70 years of age, or who have repeat surgery will have a much poorer outcome than their healthier and younger counterparts that had elective surgery. These factors also impact considerably and the length of hospitalisation.

Table 4: Mortality rates

Surgery type	Alive	Died
Aortic aneurysm (Elective)	263	5
Aortic aneurysm (Ruptured)	50	25
Carotid endarterectomy	383	4
Infra-inguinal bypass	377	25

Endovascular surgery:

Endovascular therapy has in recent times gained interest and recognition among vascular surgical units. The procedure appears to be less traumatic for the patient and most likely results in fewer complications.

An increasing number of patients will have therapeutic interventions for arterial disease performed by way of an 'endoluminal approach'. This is done via a needle puncture into an artery and the operation is then completed.

Due to such procedures being less invasive and frequently requiring a lesser depth and/or duration of anaesthetic, the complication rate at the time of the operation may be lower. Such procedures are performed in the operating theatre with X-ray equipment but increasingly vascular surgeons are doing the operations in dedicated and specially equipped radiology suites. Many forms of arterial disease are not suitable for an endoluminal approach and vascular surgeons will continue to treat arterial disease using both open operations and endovascular approaches.

The aim of the MVSA audit, in the future, is to better audit and evaluate this new technique to ensure that indeed it is a safer alternative to traditional procedures. At this time there are too few operations of this nature in the database to permit meaningful analysis. In part this reflects the fact that this Report analyses data from the vascular surgery units in Victoria's public hospitals. In public hospitals, a majority of the endovascular procedures are done by our radiological colleagues and hence, are not entered into the vascular database.

Carotid endarterectomy

Carotid endarterectomy refers to an operation in which a deposit of cholesterol in the carotid artery in the neck, that is causing a severe narrowing (typically 70% or greater), is removed to prevent a stroke. There is a carotid artery on each side of the neck and between them the carotid arteries supply 80% of the blood flowing to the brain. The operation is performed in association with control of the risk factors for arterial disease, namely:

- Lowering cholesterol
- Cessation of smoking
- Control of high blood pressure
- Control of diabetes

In addition, patients will have been commenced on anti-platelet drugs such as aspirin if there are no contraindications to the use of such agents.

The operation may be undertaken after a patient has already experienced a 'mini-stroke', more properly called a transient ischaemic attack (TIA) or a stroke. Subsequent investigation may identify the severe narrowing in the carotid artery in the neck and other possible causes have been excluded.

The other indication for the operation is in the patient who is identified with a severe narrowing but the patient has not had a symptom from the narrowing. This type of severe narrowing is often identified after the carotid artery is listened to with a stethoscope and the examining doctor hears a noise. The site and the characteristics of the noise alert the doctor to the presence of a severely narrowed artery. This suspicion is then confirmed with a duplex scan or possibly an angiogram.

The operation can be technically challenging and is seen by vascular surgeons as an excellent index of a surgeon's abilities. Whilst the operation is performed to prevent the patient from experiencing a stroke, or to prevent them having another stroke, the most common major complication of the operation is a stroke occurring during or immediately after the procedure.

Demographic data

Of the patients undergoing carotid endarterectomy approximately 70% are male. This has been the case for all years of data collection (1999-2006). The mean age for patient of both genders is 73 years. A series of figures is shown below that displays age distribution, risk factor and indications for surgery of the patients undergoing carotid endarterectomy.

Figure 1: Age distribution: Carotid endarterectomy

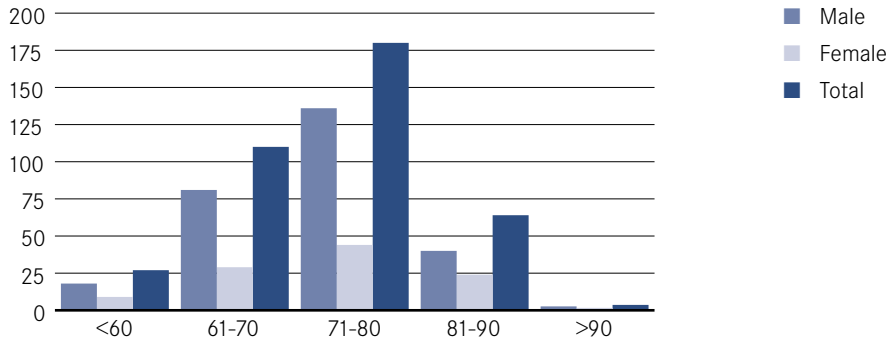


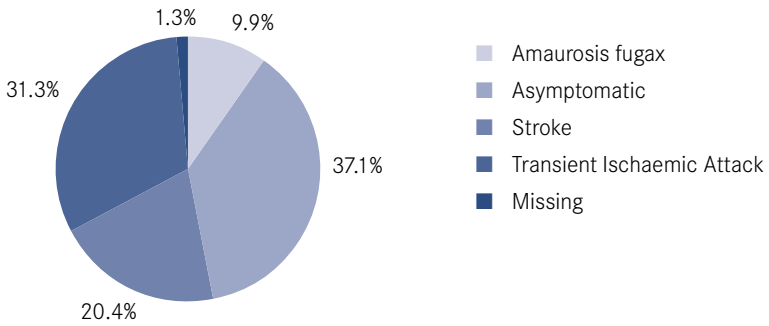
Table 5: Risk factors noted at the time of surgery

Risk factors	Rate (%)
Diabetic	26.8
Hypertension	90
Ischaemic Heart Disease	51.7
Smoking history	77.3

	Current*	Ex*	Non smokers	Missing
Smoking status (%)	13.5	57.6	20.8	8

Ex= Patients having smoked cigarettes in the past and currently are not smoking*
Current= Patients have smoked within 2 weeks of surgery*

Figure 2: Indication for carotid endarterectomy



Amaurosis fugax: A temporary loss of vision occurring in one eye. Vision loss typically lasts only seconds, but may last for hours.

Audit area 1 – Stroke rate after carotid endarterectomy

This operation is performed to prevent the patient from experiencing a stroke, or to prevent them from having another stroke. Stroke is also the most common major complication of the operation and this may occur during or immediately after the procedure. Many studies of the operation in the medical literature indicate the operative risk of a stroke with the operation needs to be less than 5% to be of benefit to the majority of patients having the operation when a previous stroke or mini-stroke is the reason for the surgery.

The contemporary literature addressing major complications following carotid endarterectomy usually combines the mortality and the permanent stroke rate. Death after the operation is infrequent and may be due to a major stroke or a post-operative heart attack ('myocardial infarction'). Of the 384 patients who had carotid endarterectomy performed during 2005-06, six experienced a stroke associated with surgery with no more than two at any hospital. This is a mean stroke rate of 1.6%. One of the patients who suffered a stroke also died.

On detailed individual analysis, all hospitals showed stroke rates below the acceptable upper limit. Ongoing analysis of performance is carried out to identify the occurrence of increased and unacceptable complication rates.

At several sites the number of operations performed during any one year is small. When statistical analyses are performed on these data, there are no significant differences in stroke rate between the various institutions. This lack of 'significant difference' means that the differences in stroke rate as observed between hospitals could have arisen by random chance rather than the differences arising from truly different rates due to surgical technique, anaesthetic technique or patient selection. In general, it requires approximately 100 operations at each hospital to be able to make meaningful comparisons between hospitals. Even at the larger hospitals this will require data to be accumulated over three years.

Nerve damage with the operation:

During the operation of carotid endarterectomy there are several nerves that are at risk of being damaged, which may cause disability. The procedure is performed with an incision on the side of the neck, overlying the artery. Dividing the nerve that supplies sensation below the jaw line is unavoidable. This results in an area of numbness that may recover over several months or which may be permanent.

In exposing the artery, a small nerve that runs and dips below the jaw line can be damaged by sharp incision or by vigorous retraction, resulting in paralysis of the small muscles around the angle of the mouth. To clear the artery of the cholesterol deposit, approximately 7cm of the carotid artery is exposed and carefully separated from the surrounding structures, including several nerves,

damage to which the surgeon tries to avoid. Damage to these nerves can result in a hoarse voice or difficulty swallowing or paralysis of the muscles of the tongue on the side of the operation. The risk of damage to one or more of these nerves is increased if there has been previous surgery on the same area or previous radiotherapy to the region for an unrelated condition. The patient will be warned of these increased risks during the obtaining of informed consent by the surgeon.

Balloon dilatation and stent insertion in the carotid artery:

The technology is now available to treat some patients with a severe narrowing in the carotid artery using an endovascular approach via the artery in the groin. At the present time very few of the procedures have been performed and the number of patients on the vascular database is too few to permit statistical analysis. Once adequate numbers have been collected, the procedure will be analyzed separately from the results from the open operation.

Infra-inguinal bypass

Similar to the carotid arteries in the neck and the coronary arteries in the heart, the arteries in the lower limbs can become partly or completely blocked by cholesterol deposits. The patients affected by arterial disease are most often the elderly who have multiple associated conditions including heart disease, diabetes, hypertension and smoking-related lung disease.

When the leg arteries are blocked the patient may experience no symptoms or have pain in the legs when walking. This is referred to as claudication. This pain can range from mild to severe. Ulceration or gangrene of the leg tissue can also occur. When the symptoms of claudication are severe, or if the survival of the leg is threatened, then the blood flow to the leg will need to be improved by either:

- Angioplasty (stretching the wall of the artery with a balloon)
- Bypass operation, or
- A combination of both.

Bypass is performed if the vessel disease is advanced or unsuitable for angioplasty. A graft is inserted to bypass the blockage and conduct blood from the groin artery above the blockage to the artery at the knee level below the blockage. This procedure is called an infra-inguinal (below the groin) bypass. The graft used for the bypass is usually a vein from the leg. Another option used where venous grafting is unsuitable or unavailable, involves the use of a vein from the arm or a synthetic (plastic) graft.

Demographic data

Of the 440 patients undergoing infra-inguinal bypass, approximately 70% were male. The mean age for females was 76 years which is marginally older than for males (73.1 years). The mean postoperative length of stay for all infra-inguinal bypasses was 13 days (median=8).

A series of figures is shown below that displays age distribution, risk factor and indications for surgery of the patients undergoing infra-inguinal bypass.

Figure 3: Age distribution: Infra-inguinal bypass

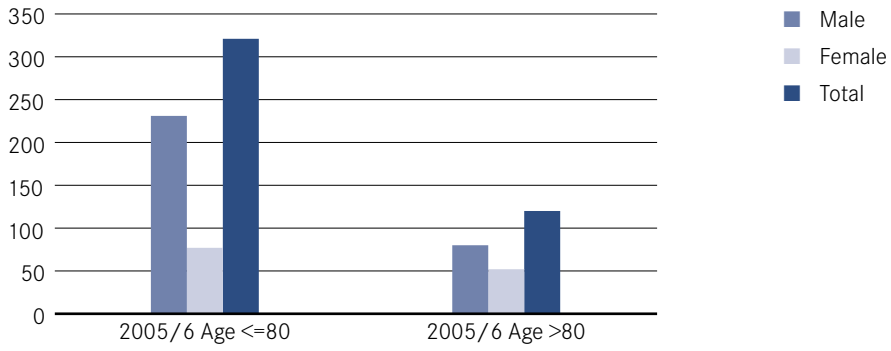


Table 6: Risk factors noted at the time of surgery

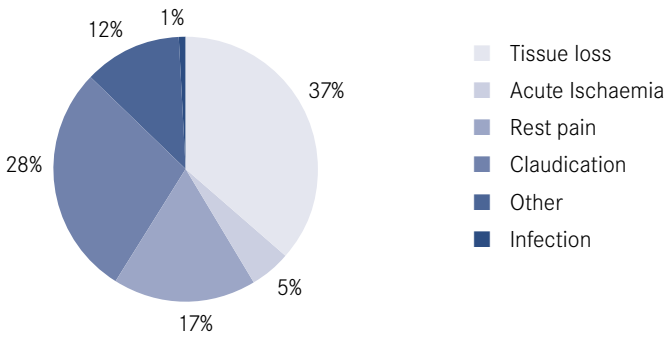
Risk factors	Rate (%)
Diabetic	42.4
Hypertension	83.4
Ischaemic Heart Disease	53.2
Smoking history	70.2

	Current*	Ex*	Non smokers	Missing
Smoking status (%)	17.1	53.3	21.8	7.8

Ex= Patients having smoked cigarettes in the past and currently are not smoking*

Current= Patients having smoked cigarettes in the past and have smoked within 2 weeks of surgery*

Figure 4: Indication for infra-inguinal bypass surgery



The desired outcome following infra-inguinal surgery is the discharge of the patient from hospital with a functioning bypass graft and a limb that has been saved from amputation. The graft occlusion rate is the main criterion chosen for review. Sometimes the degree of disease is so advanced that the leg needs to be amputated to save the patient's life, and sometimes a leg has to be amputated despite a functioning bypass if the tissue loss is too advanced.

When a bypass graft blocks before the patient is discharged from hospital, the usual cause is a technical error. Some patients will have a blocked graft because the disease in the arteries is too advanced or because the graft used is unsatisfactory, but an attempt is still made to save the leg. The patient may be returned to the operating theatre and the graft may be revised to achieve a functioning bypass. There are other factors which the MVSQI has identified that result in a higher graft blockage rate during the period 2005-06:

- Grafting onto the calf or foot arteries,
- Use of arm vein as the bypass graft.

All bypasses performed during 2005-06 have been examined to establish the rate of graft blockage when performed for claudication and for tissue loss. The rate of amputation following infra-inguinal bypass has also been analysed.

Occlusion after bypass for claudication = 3.2% (raw data)
Occlusion after bypass for tissue loss = 4.3% (raw data)
This was not statistically different.

The MVSQI assesses the success rate of surgery for infra-inguinal bypass. It is important to recognise that comparison of performance for infra-inguinal bypass outcomes with other publications is difficult because most series report results at 30 days, whereas the MVSQI assesses results at the time of discharge.

Audit area 2– Occlusion following infra-inguinal bypass

The raw or unadjusted rate of graft occlusion following infra-inguinal bypass for all indications was 4.3%. On more detailed examination, using advanced statistical techniques (cumulative sum analysis), no hospital recorded occlusion rates that were unacceptable. The raw figures are shown below. A more detailed comparison will be possible as the number of recorded procedure increase.

Table 7: Occlusion following all infra-inguinal bypasses

Hospital code	Occlusions	Total bypasses	Occlusion (%)
1	0	14	0
2	1	56	1.8
3	8	67	11.9
4	1	25	4
5	0	52	0
6	2	47	4.3
7	0	12	0
8	3	44	6.8
9	3	53	5.7
10	0	14	0
11	1	33	3
12	0	23	0
Total	**19**	**440**	**4.3**

Audit area 3– Amputation following infra-inguinal bypass

Amputation rate after bypass was 1.8%, and no patients with claudication lost a limb. All amputations occurred when the indication for surgery was either tissue loss or acute ischaemia.

Risk adjustment has been applied to this outcome as with all previous infra-inguinal bypass data and further statistical analyses shows that there were no hospitals with poorer than expected results. Graft occlusion, prosthetic bypass, tissue loss and arm vein bypass were significant predictors for limb loss in order of importance in combined analysis of the 2004-05 and 2005-06 dataset.

Aortic aneurysm surgery

An abdominal aortic aneurysm is an enlargement, dilatation or bulging of the main artery (aorta) in the abdomen. This results from a weakening of the wall of the normal aorta. The majority (96%) begin below the renal (kidney) arteries. The risk of rupture of the aneurysm increases progressively with increasing aneurysm size. Once the maximum diameter of the aneurysm exceeds 5.5 centimetres the risk of rupture rises sharply. The expected surgical mortality after elective repair of non-ruptured aortic aneurysms is relatively low while surgical repair following rupture of an abdominal aortic aneurysm is associated with significant morbidity and mortality. Aneurysms are encountered in three states; elective (unruptured), painful (warning of impending rupture) and ruptured.

The traditional technique of open surgical repair of abdominal aortic aneurysm, which has been performed over the last fifty years, replaces the aneurysmal artery with an artificial or prosthetic (usually Dacron) graft. The aorta above and iliac arteries below the aneurysm are temporarily clamped off. A graft is then sewn to the non-aneurysmal artery above and below the aneurysm. The graft may be either a 'tube' (straight) or 'trouser' (bifurcated) configuration depending on the extent of the aneurysmal disease. Open surgical repair was performed in all cases of ruptured aneurysms or a bifurcated or a 'trouser' graft sewn to each of the iliac arteries.

An alternative to open surgical repair has been practiced since 1991 using a minimally invasive 'keyhole' approach. In this procedure a prosthetic stent graft, which is mounted on a metal skeleton, is introduced via the femoral arteries in the groin and placed in position within the aneurysm like an 'internal sleeve'. Blood then flows from the normal, non-aneurysmal aorta through the stent graft and on into the arteries below the aorta. The long-term results of endovascular aortic repair (EVAR) continue to be evaluated worldwide. More recently, ruptured aortic aneurysms have been treated with endografts and early encouraging results have been reported.

Emergency admissions for conditions that have the potential to deteriorate quickly, to the point that it may become a life or limb threatening event, will have a greater risk, such as ruptured versus elective aortic aneurysm surgery. Nearly a quarter of all the 368 operations for aortic aneurysm repair (22%) are performed as emergency procedures (includes painful and infected aneurysms).

Demographic data

The median age for the aortic aneurysm group was 76 years with 85% being male. This distribution is the same whether the operations are elective or ruptured.

Figure 5: Age distribution: Aortic aneurysm repair (Elective)

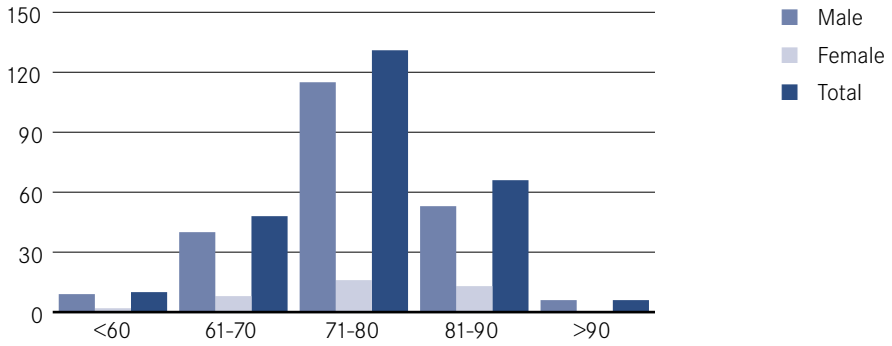


Figure 6: Age distribution: Aortic aneurysm repair (Ruptured)

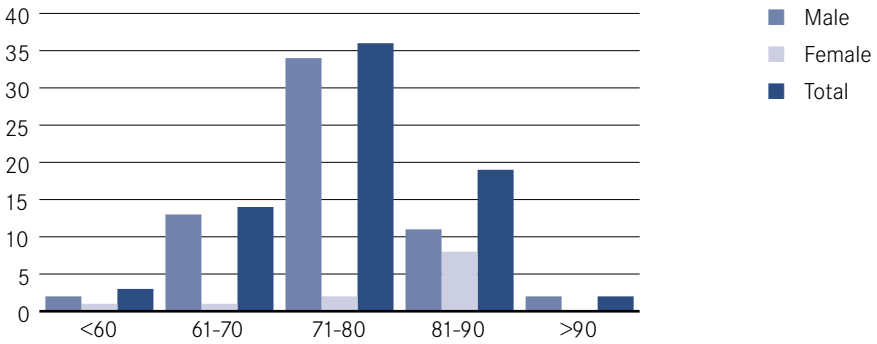
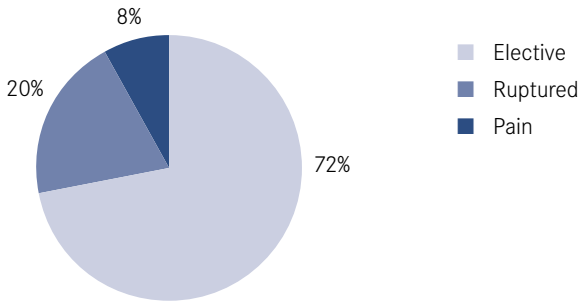


Table 8: Risk factors noted at the time of surgery

Risk factors	Elective		Ruptured	
	Present (%)	Absent (%)	Present (%)	Absent (%)
Hypertension	78.5	21.5	78.8	21.2
Ischaemic Heart Disease	56	44	47.7	52.3

Figure 7: Indication for aortic aneurysm repair



Audit area 4 – Death rate after repair of aortic aneurysm repair

The overall crude (non risk-adjusted) mortality for all patients (368) undergoing aortic aneurysm surgery was 8.4%.

Open surgical repair

Open surgical repair was performed in 232 patients. The elective 'open' surgery group (139 patients) had a mortality rate of 7.2%. This includes thoracic (128) and suprarenal aneurysms (11). If one looks only at the patients with an infra-renal aneurysm, the mortality was 4.7%. As expected the group of patients (n=74) who underwent repair of a ruptured aneurysm had a much higher mortality rate of 24.3%. This higher rate is expected given the morbidity associated with the rupture of aneurysm. 1 of the 20 patients operated on for a painful aneurysm treated by open operation died.

Endovascular repair

Endovascular repair was performed in 140 patients. Elective endovascular repair had a similarly low mortality of 0.8% in 122 patients. These results are comparable to currently accepted international standards. If endovascular repair proves to be durable and the need for secondary interventions is small, this may become the method of choice for treating anatomically suitable aneurysms. Four patients were treated endoluminally for rupture with 2 mortalities.

Detailed statistical analysis (Logistic regression) of the results showed that a higher risk of death occurs in patients aged over 80 years of age and where suprarenal cross clamping (where the clamp is placed above the kidney arteries) was required to control bleeding during open surgery. Rupture of an aneurysm also carries a higher risk of death, as does intra-operative blood loss of more than 3 litres. Further statistical analysis also showed that all reporting hospitals performed satisfactorily during 2005-06.

Table 9: Mortality rate for open aortic aneurysm repair

Hospital code	Elective		Emergency	
	Cases	Mortality (%)	Cases	Mortality (%)
1	7	0	5	0
2	24	3(12.5)	7	2 (29)
3	24	3(12.5)	12	4 (33)
4	5	0	1	0
5	9	0	4	2 (50)
6	7	0	8	4 (44)
7	13	0	6	2 (33)
8	5	1 (20)	3	2 (67)
9	22	3(13.6)	10	4 (40)
10	11	0	5	0
11	6	0	6	1 (17)
12	6	0	3	1(33)
Total	**139**	**10 (7.2)**	**70**	**22 (31)**

Post-operative length of hospital stay depends upon the indication for aneurysm surgery and the method of treatment. For open elective aneurysm bypass surgery it is 7 days (median). For ruptured aneurysms overall it is 12 days, but as nearly a third of patients die (usually early post-operatively or intra-operatively) the median postoperative stay is 3 days for patients who die, compared to 16 days for survivors. Thus, these patients place much larger demands on health care resources than electively treated patients. Endoluminally treated patients have the shortest post-operative stay, as expected, with a median duration of 4 days.

Conclusion

This report assures the community that they receive a high standard of treatment for arterial disease in Victorian public hospitals. The report has focused on the three most common surgical procedures used to treat cerebrovascular disease, aortic aneurismal disease and occlusive disease of the lower limbs. Performance monitoring will continue to ensure that this high standard is maintained and opportunities for improvement are identified.

Low numbers of procedures, such as with carotid endarterectomies, make analysis difficult. Similarly, when the infra-inguinal data was checked for each individual hospital there were no identifiable problems but the number of operations in this group was also low at some hospitals. It may be only when the subcategories of procedures are analysed separately that a problem appears, as there is no detectable issue of competence when the group as a whole is assessed. It is, therefore, important that results from individual surgeons are reviewed separately from consolidated hospital results. This helps to ensure the identification and management of higher than expected complication rates.

A careful process of clinical evaluation by experienced clinicians has been adopted by the MVSA as the definitive step in assessing whether or not there has been unacceptable performance. This has been refined after lengthy debate. Membership of the MVSA implies compliance with this process.

The publication of this report demonstrates the value of having a professional group such as the MVSA auditing clinical performance. This has only been possible because of the involvement of the Department of Human Services. This is expected to be an ongoing arrangement in order to ensure that Victorians receive the highest possible quality of health care by vascular units in the state.