



**Patients' preference between two competing treatments:
carotid stenting and carotid surgery**

Aigul Kabayeva, MD (Neurology)

Supervised by Professor Martin Brown

Department of Stroke Medicine

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Institute of Neurology

University College London

(Queen Square, London WC 1M 3BG)

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TABLE OF CONTENTS

Acknowledgements	2
Table of contents	3
Abbreviations	4
Abstract	5
Introduction	6
Methods	14
Results	16
Discussion	33
Conclusion	39
References	40
Appendix:	
1, Questionnaire	45
2. Patient Information Sheet	53
3. Pictures	54

ABBREVIATIONS

CAS – carotid artery stenting

CEA – carotid endarterectomy

ICSS – International Carotid Stenting Study

CAVATAS – Carotid and Vertebral Artery Transluminal
Angioplasty Study

ECST – MRC European Carotid Surgery Trial

NASCET – North American Symptomatic Carotid Endarterectomy
Trial

SPACE – Stent-Protected Angioplasty versus Carotid
Endarterectomy

GPN – glossopharyngeal nerve

VN – vagus nerve

ECAS – extracranial carotid artery stenosis

CaRESS – Carotid revascularization using Endarterectomy or
Stenting Systems Study

EVA-3S – Endarterectomy versus Angioplasty in Patients with
Symptomatic Severe carotid Stenosis trial

ACAS – Asymptomatic Carotid Atherosclerosis Study

ACST – Asymptomatic Carotid Surgery Trial

SAPPHIRE – Protected carotid artery stenting versus endarterectomy
in high-risk patients study

ABSTRACT

There are two competing treatments for atherosclerotic stenosis of the carotid artery, a major cause of stroke; carotid endarterectomy (CEA) and carotid artery stenting (CAS). There have been various studies of the comparative medical merits of both methods. However, there is a lack of research on factors affecting patients' preference, and the aim of this pilot- study was to attempt to determine the factors contributing to this.

15 patients, including International Carotid Stenting Study participants, and those from the Stroke unit ward and outpatients clinic, were given a standard questionnaire, covering safety, side-effects, personal fears and willingness to pay. After reading an information sheet, the patients were asked to fill in the questionnaire without intervention from myself.

A 2 to 1 majority of interviewees stated a preference for stenting over surgery. The strongest factors in patients' choice appeared to be perceived risk, concern over side effects, and anxiety in regard to type of anaesthesia.

It is clear that a larger study is required, perhaps with some modification to the questionnaire and a more representative sample of interviewees.

INTRODUCTION

Stroke is defined as “..rapidly developing clinical signs of focal (or global) disturbance of cerebral function with symptoms lasting 24 hours or longer or leading **to** death with no apparent cause other than vascular origin”. (Senple *et al*, 1999), and is the cause of 12% of deaths in the UK, and 7% in the USA. Also, when not fatal it is the single largest cause of an acquired adult physical disability in this country. “It is estimated that there are 4,5 million deaths a year from stroke in the world and over 9 million stroke survivors. Almost one in four men and nearly one in five women aged 45 years can expect to have a stroke if they live to their 85th year.” (Wolfe, 2000).

A major cause of stroke is atherosclerotic stenosis of the carotid artery.

With regards to the treatment, historically the standard treatment has been Carotid Endarterectomy, a surgical operation performed under a general anaesthetic, in which a diseased part of the artery is cut out through an incision in the neck (CEA – figure 1, see Appendix).

In 1954, the first well-publicized carotid operation reported the successful treatment of a 66-year-old woman who had experienced 33 episodes of right hemiparesis secondary to left carotid stenosis. More recently, however, the technique of Carotid Stenting has been introduced. This is derived from the technique of percutaneous transluminal angioplasty (PTA). A small tube of wire mesh, called stent, is placed in the artery through a catheter in the groin under local anaesthetic, and opened out to keep the artery open. This represents the first real alternative to CEA, offering greatly reduced invasiveness, and has proved to be of considerable interest.

CAROTID ENDARTERECTOMY

CEA has become the “gold standard treatment” for atherosclerotic stenosis. More than 100,000 such operations were carried out in the USA in 1985 alone.

A significant reduction of risk of stroke following carotid surgery has been shown by both the European Carotid Surgery Trial (ECST) and the North American Symptomatic Carotid Endarterectomy Trial (NASCET). These have established CEA as the predominant treatment for atherosclerotic stenosis. The NASCET showed a

cumulative reduction of risk of ipsilateral stroke within 2 years from 26% to 9%.

However, with the required neck incision, the treatment is highly invasive, giving rise to various risks and side effects.

Firstly, there are potential wound complications, such as wound haematoma, requiring re-exploration in some cases.

Secondly, there can be superficial nerve injury.

Thirdly, because of the requirement for general anaesthesia, there is a small risk of myocardial infarction as it is common for patients with carotid stenosis to also have ischemic heart condition.

Fourthly, there is a risk of actually inducing a stroke with the procedure.

Finally, there is a risk of cranial and cervical nerve injuries. A study by Ballotta et al showed that cranial nerve injury after CEA was in fact more common than had previously been thought. They concluded that “this is a common occurrence and can be classified as major or minor, depending on the severity of the clinical consequences.”(Ballotta *et al*, 1999). Symptoms can include severe difficulty with swallowing and speech, and atrophy of the denervated portion of the tongue.

“Bilateral palsy of the hypoglossal nerve is followed by life threatening upper airway obstruction in the supine patient, dysphasia

and difficulty swallowing. Injury to Glossopharyngeal Nerve (GPN) can result in symptoms ranging from mild dysphagia to severe recurrent aspiration, respiratory failure, and malnutrition. Moreover, the GPN gives rise to the carotid sinus nerve, also known as Hering's nerve. Its stimulation may be responsible for severe and intractable postoperative hypotension by a reflex arc through the VN (Vagus Nerve). Section of Hering's nerve can lead to postoperative hypertension, with an increased risk of cerebral haemorrhage or edema, and also cervical haematoma.”(Ballotta *et al*, 1999).

CAROTID STENTING

Stenting is a relatively new treatment for stenosis, and avoids some of the risks associated with carotid endarterectomy. It offers clear advantages in patient comfort, and reduced requirement of hospital stay.

There is no neck incision, and no general anaesthesia with all its attendant drawbacks. It has the additional benefit of not being restricted to the cervical portion of the carotid artery; stenting can be simultaneously carried out on vertebral and coronary arteries.

The above mentioned risk of myocardial infarction is significantly reduced in comparison with CEA, so its use is desirable in elderly patients and those with coexisting coronary artery disease.

Also “general anaesthesia is not required, cranial palsies are not sequelae” and “the technique can be safely applied to restenotic lesions and in fibromuscular dysplasia” (Taylor *et al*, 2003).

There is normally an economic benefit of CAS over CEA due to a combination of the above factors and the reduced requirement for intensive care treatment.

The disadvantages of stenting include:

- induced stroke; varying results have been obtained comparing rates of major stroke within 30 days of treatment by CAS and CEA. Most of the studies concluded that the complication rates associated with CAS are higher than with CEA.

However, Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) in 2001, found no significant difference for major stroke or death.

- Slower return to full activity. Brook et al found that complications arising from CAS proved more debilitating than those from CEA due to the limiting nature of groin pain in comparison with neck pain.
- Lack of information regarding stroke recurrence.

There have been a number of trials carried out comparing CAS and CEA. These include Protected carotid artery stenting versus endarterectomy in high-risk patients study (SAPPHIRE), MAVERIC,

Carotid revascularization using Endarterectomy or Stenting Systems Study (CaRESS), CAFÉ, CSSA, ARCHER, SHELTER, Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE), CABERNET, Endarterectomy versus Angioplasty in Patients with Symptomatic Severe carotid Stenosis trial (EVA-3S), North American Symptomatic Carotid Endarterectomy Trial (NASCET), Asymptomatic Carotid Atherosclerosis Study (ACAS), ACST, Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS).

All of these tend to conclude that CEA should be retained as the principle method of treatment for carotid artery stenosis. CAVATAS was the only study which failed to show a significant difference of major stroke within 30 days of treatment. “CAVATAS demonstrated to a sceptical surgical audience that following successful CAS, three year outcomes were probably no different to CEA” (Naylor, 2007).

A summary of results from some of the largest randomised trials on symptomatic patients can be seen in the table below;

Table 1 The rate of death or stroke 30 days after procedure

TRIAL	CAS	CEA
SPACE	6.84%	6.34%

EVA-3S	9.6%	3.9%
CAVATAS	10.0%	9.9%

It should be noted that Ross Naylor has criticised “systematic failure to achieve randomisation targets (thereby preventing any prospects of a statistically meaningful outcome) amid a milieu of corporate and individual conflicts of interest” and asserts that “the studies provide surgeons and interventionists with evidence to support their personal prejudice. Surgeons who think that SPACE and EVA-3S have settled the debate and restored CEA to primacy are deluded! Similarly, those interventionists who comfort themselves by writing off SPACE and EVA-3S as maverick trials are also blind to reality. The most obvious reason why the results of SPACE and EVA-3S were poorer than SAPPHIRE is that they randomised *recently symptomatic* patients, i.e. high risk for stroke. That description could never apply to the SAPPHIRE cohort. Finally, the main reason why ECST, NASCET, ACAS and ACST influenced clinical practice was because they randomised large numbers of patients. CEA and CAS will inevitably have a complimentary role. It is therefore imperative that we support the two remaining trials that are randomising recently symptomatic patients (ICSS in Europe and CREST in North America)” (Ross Naylor, 2007).

The aim of ICSS is “to compare the risks, benefits and cost effectiveness of a treatment policy of referral for carotid stenting compared with referral for carotid surgery.”

Notwithstanding all the above research comparing the two different treatments, there is a perceptible gap in the field of patients’ preference, which has not been studied extensively. One large study was published in 2003, the purpose of which was “to determine and analyse patient preferences for the treatment of extracranial carotid artery stenosis” (Warren *et al*, 2003). The study concluded that patients more often chose CEA over CAS for revascularization of Extracranial carotid artery stenosis (ECAS). Another study noted that “patients would choose a less invasive approach to an open procedure if clinical results were equivalent.” And very often patients are “driven away from surgery owing to prejudices toward any surgical procedure, often because of a fear of general anaesthesia.” (Taylor *et al*, 2003).

The aim of my pilot-study is to determine the factors contributing towards patients’ preference between two competing treatments; carotid stenting vs carotid surgery, which are under comparison in a randomised trial, known as the International Carotid Stenting Study (ICSS).

METHODS

This study was designed as a pilot study, in conjunction with ICSS.

I sought to elicit and analyse patients' preferences with regard to the choice between CAS and CEA.

This was accomplished with a standard questionnaire (see Appendix) used in an outpatient setting and in the Stroke unit wards at The National Hospital for Neurology and Neurosurgery. The questionnaire was based on the list of possible reasons for treatment choice, such as safety, cost, side effects, fear of surgery (for religious or personal reasons, lack of knowledge, educational experience, past experience of surgery of relatives or friends).

All patients were asked to read an information sheet (see Appendix) and then to answer questions without intervention from myself.

However, a semi-structured interview was conducted afterwards if required, in order to explore the above topics in further detail.

For inclusion in this study, patients had to be 18 years or older, willing to participate, and to have suffered stroke, or transient ischemic attack (TIA) within the last 5 years. ICSS follow-up patients were also included.

Exclusion criteria included; unwillingness to participate, unsuitability for study because of dementia or severe psychiatric illness, inability

to understand due to dysphasia or cognitive impairment, insufficient comprehension without services of a translator.

ICSS had pre-existing ethical committee approval. I was added as an investigator with approval of the local ethics committee to conduct this substudy within ICSS. Verbal consent from all participants was obtained. .

Simple statistical comparisons were made between the proportions of subjects answering. Two statistical tests for small samples – the Wilcoxon signed rank test and the Fisher exact test – were carried out.

RESULTS

15 patients participated in this study. The average age of the participants was 70. There were 7 men and 8 women.

There were 8 ICSS patients, 2 patients from stroke unit ward and 5 outpatients.

Below are their answers to the following questions.

1. What treatment would you prefer: stenting or surgery?

The percentage of patient who preferred stenting is 66.6% (10/15).

The percentage of patients who preferred surgery is 33.3% (5/15).

2. Could you score each treatment according to you preference on a linear scale of 1 to 10 where:

1 – I would not have treatment under any circumstances.

10 – I am extremely keen to have this treatment.

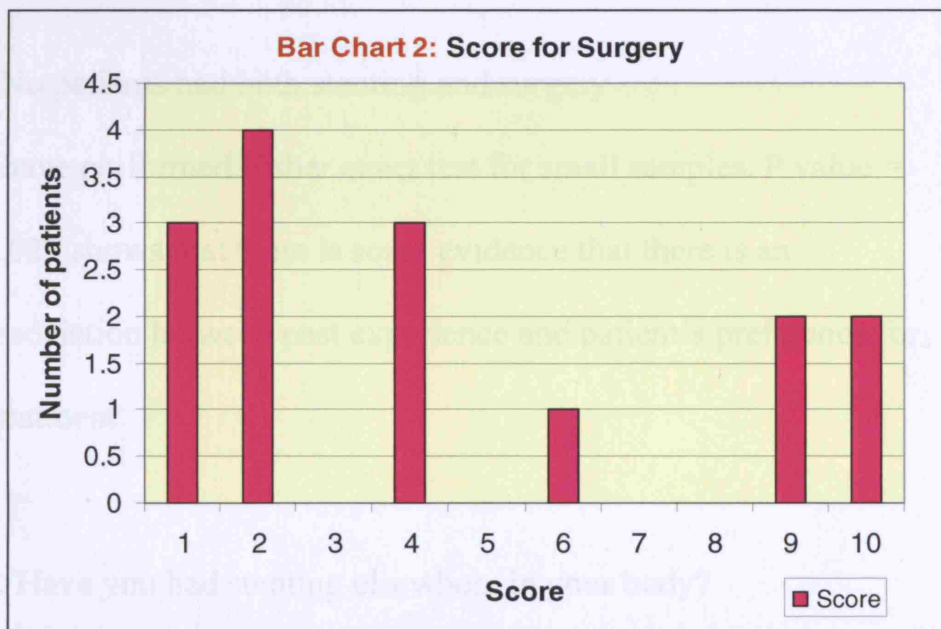
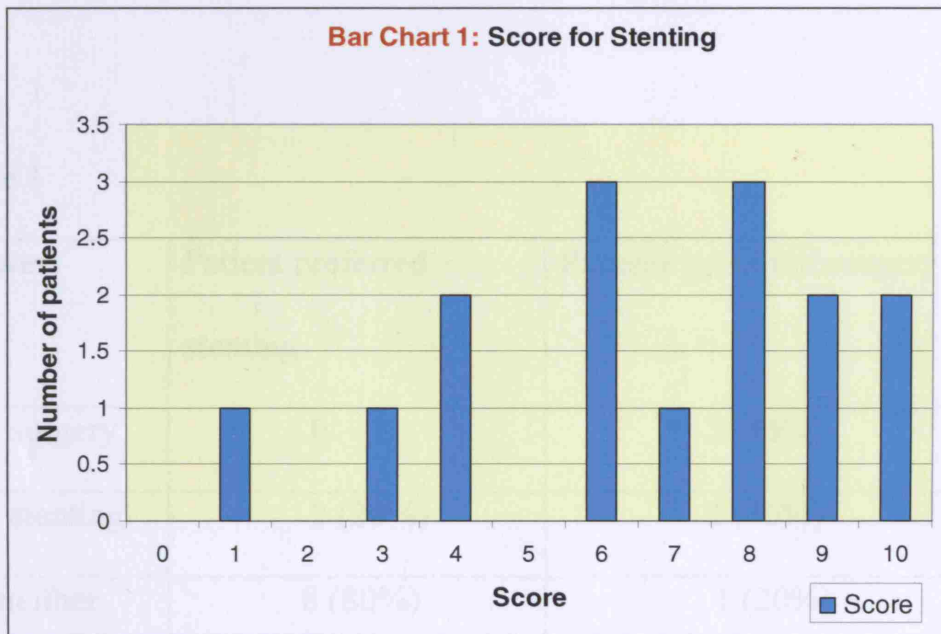
Median score for the group who preferred stenting is 7.

Median score for the group who preferred surgery is 4.

Median of difference in scores (score for stenting minus score for surgery) is (+3), which indicates that on average people tend to give a lower score for surgery.

I have performed Wilcoxon signed rank test on the differences in scores.

P value of 0.09 tells us that there is no strong evidence of difference in score between these two treatments.



However, the bar charts show a greater weighting of positive results for stenting as compared to surgery.

3. Have you had any of these treatments before?

Answer: Yes, surgery.
Yes, stenting.
Yes, both.
No, neither

Table 1

Answers	Patient preferred stenting	Patients preferred surgery
Yes, surgery	0	2 (40%)
Yes, stenting	2 (20%)	2 (40%)
No, neither	8 (80%)	1 (20%)

*No patients had both stenting and surgery

I have performed Fisher exact test for small samples. P value = 0.023 shows that there is some evidence that there is an association between past experience and patient's preference for treatment.

4. Have you had stenting elsewhere in your body?

Answer: Yes
No

Only 2 patients had had stenting elsewhere in their body so no

further analyses were carried out for this question.

5. Have you had major surgery elsewhere in your body?

Table 2

Answers	Patients preferred stenting	Patients preferred surgery
Yes	9 (90%)	4 (80%)
No	1 (10%)	1 (20%)

In both groups the majority of the patients had had major surgery.

It is a very slight difference between percentage of patients who had major surgery in both groups (90% and 80%).

6. Have any member of your family or close friends had one of these treatments?

Answer: Yes

No

In both groups the majority of the patients' members of the family or close friends have not had any of these treatments.

7. Have you experienced either general or local anaesthesia?

- Answer: Yes, local.
- Yes, general.
- Yes, both.
- No, neither.

Table 3

Answers	Patients preferred stenting	Patients preferred surgery
Yes, local	1 (10%)	0
Yes, general	3 (30%)	3 (60%)
Yes, both	6 (60%)	2 (40%)

Of those who preferred stenting, 60% have experienced both types of anaesthesia, and of those who preferred surgery, 40% have had general and local anaesthesia.

8. Given a necessity to have anaesthesia, which of these two would you prefer?

Table 4

Type of anaesthesia	Patients preferred stenting	Patients preferred surgery
Local	6 (60%)	2 (40%)
General	4 (40%)	3 (60%)

60% (6) of patients who preferred stenting would prefer local anaesthesia which is usually used for stenting.

60% (3) of patients who preferred surgery would prefer general anaesthesia which is usually used for surgery.

9. If you had local anaesthesia would you be concerned about the following?

- a. being able to watch the whole procedure
- b. being able to feel pain during the surgery
- c. past experience with local anaesthesia

In the group of patients who preferred stenting:

60% (6) are not concerned about being able to watch the whole procedure.

90% (9) are not worried about being able to feel pain during procedure.

100% are not worried about past experience with local anaesthesia.

In the group of patients who preferred surgery:

Table 5

Main concerns	Yes	No
Being able to watch the whole procedure	4 (80%)	1 (20%)
Being able to feel pain	3 (60%)	2 (40%)
Past experience with local anaesthesia	2 (40%)	3 (60%)

80% (4) of patients who preferred surgery are worried about being able to watch the whole procedure.

60% (3) are worried about being able to feel pain during surgery.

40% (2) are worried about past experience with general anaesthesia.

10. If you had general anaesthesia would you be worried about the following?

For patients who preferred stenting:

Table 6

Main concerns	Yes	No
Knife incision in your neck	4 (40%)	6 (60%)
Appearance (scar after surgery)	2 (20%)	8 (80%)
Past experience with general anaesthesia	4 (40%)	6 (60%)

40% (4) of patients who preferred stenting are worried about knife incision in their neck.

20% (2) are worried about scar after surgery.

40% (4) are worried about past experience with general anaesthesia.

For patients who preferred surgery

Table 7

Main concerns	Yes	No
Knife incision in your neck	1 (20%)	4 (80%)
Appearance (scar after surgery)	1 (20%)	4 (80%)
Past experience with general anaesthesia	0	5 (100%)

80% (4) of the patients who preferred surgery are not worried about knife incision in their neck.

80% (4) are not worried about the appearance (scar after surgery).

100% are not concerned about past experience with general anaesthesia.

11. Are you worried about the side-effects of treatment?

- very worried
- somewhat worried
- hardly worried
- not worried at all

For stenting: bruising or blood clot in the groin, temporary discomfort or pain in the neck or groin.

In the group of patients who preferred stenting:

60% (6) are somewhat worried

40% (4) are hardly worried

In the group of patients who preferred surgery:

20% (1) of patients are **very worried** about stenting side effects

40% (2) are somewhat worried

40% (2) are hardly worried.

Are you worried about side effects of surgery: permanent scar on the neck blood clot at the side of the incision, numbness and weakness of the face, problems with speech and swallowing.

In the group of patients who preferred stenting:

30% (3) are **very worried** about side effects of surgery.

70% (7) of patients are somewhat worried.

In the group of patients who preferred surgery:

20% (1) are **very worried** about side effects of surgery.

40% (2) are somewhat worried.

40% (2) are hardly worried about side effects of surgery.

More patients from group of patients who preferred stenting are very worried about side effects of surgery compared to the group of patients who preferred surgery (30% vs 20%).

Majority of patients from the group who preferred stenting are somewhat worried about side effects of surgery compared to the group of patients who preferred surgery (70% vs 40%).

Wilcoxon signed rank test has been preformed. P value = 0.02 shows that there is some evidence of a difference in how worried patients who preferred stenting, are about the side effects of the two procedures (stenting vs surgery).

13. Do you consider carotid stenting:

very risky

somewhat risky

hardly risky

not risky at all

Patients who preferred stenting:	Patients who preferred surgery
----------------------------------	--------------------------------

	40% found stenting very risky
--	-------------------------------

50% found it somewhat risky	40% found it somewhat risky
-----------------------------	-----------------------------

40% found it hardly risky	20% found it hardly risky
---------------------------	---------------------------

10% -not risky at all	0% - not risky at all
-----------------------	-----------------------

14. Do you consider carotid surgery:

very risky

somewhat risky

hardly risky

not risky at all

Patients who preferred stenting	Patients who preferred surgery
---------------------------------	--------------------------------

20% found surgery very risky	20% found surgery very risky
------------------------------	------------------------------

80% found it somewhat risky	20% found it somewhat risky
-----------------------------	-----------------------------

0% found it hardly risky	40% found it hardly risky
--------------------------	---------------------------

0% -not risky at all	20% - not risky at all
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Wilcoxon signed rank test has been performed. P value = 0.01

shows evidence that there is difference in how risky patients who

preferred stenting found each procedure (stenting vs surgery).

15. Now we would like to know what level of risk of stroke you would be prepared to take when considering the treatment.

Please consider the following risks of stroke at the time of the treatment and think if you would still prefer one treatment or if you would change your mind. Assume that both are equally good at preventing stroke

Tables for risk of having a stroke caused by the treatment:

Treatment	Number of patients having a stroke for every 100 patients treated
stenting	10 in 100
surgery	5 in 100

What treatment would you prefer? stenting

surgery

Treatment	Number of patients having a stroke for every 100 patients treated
stenting	9 in 100
surgery	5 in 100

What treatment would you prefer? stenting

Surgery

Treatment	Number of patients having a stroke for every 100 patients treated
stenting	8 in 100
surgery	5 in 100

20% (2) switched to surgery but returned back to stenting after risk of developing stroke after surgery and stenting became the same 5 (risk 5%).

15.16. If you had to contribute to the cost of the treatment how much more would you pay for your preferred treatment?

Surgery	£5	£10	£50	£100	£500	£1000
Stenting	£5	£10	£50	£100	£500	£1000

In the group of patients who preferred surgery:

Median amount for surgery is £500

Median amount for stenting is £5

Wilcoxon signed rank test has been performed. P value = 0.04 shows evidence that there is a difference in how much patients who preferred surgery are willing to pay for surgery vs stenting.

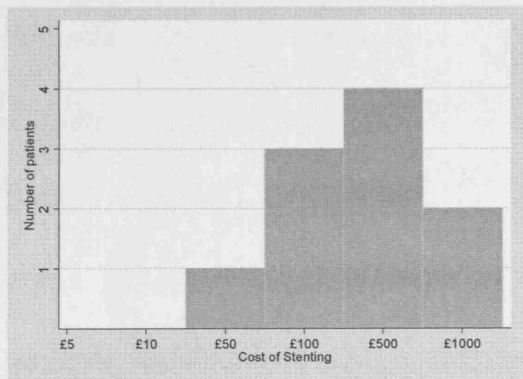
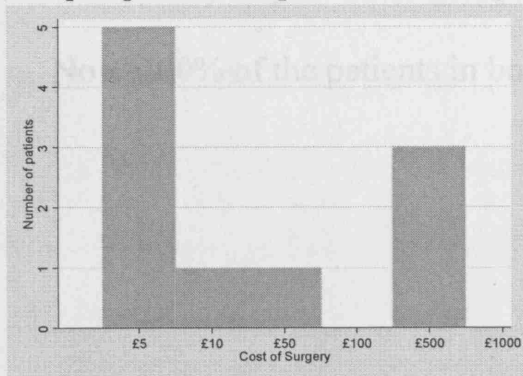
In the group of patients who preferred stenting:

Median amount for stenting is £500

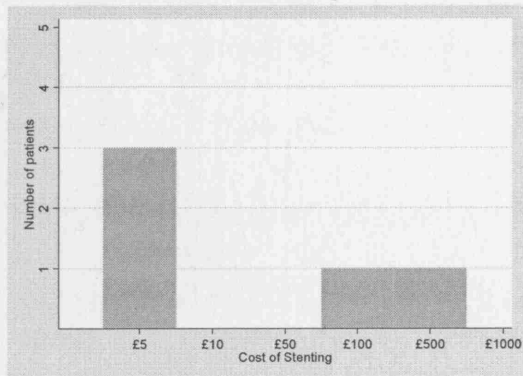
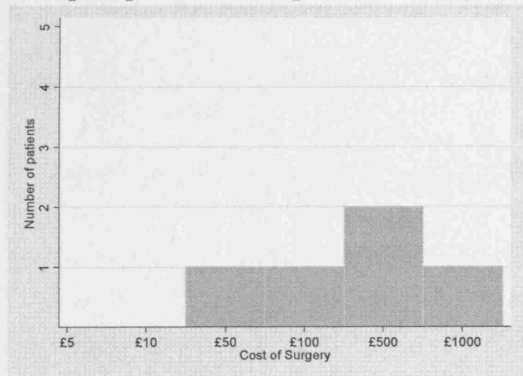
Median amount for surgery is £7.5

Wilcoxon signed rank test has been performed. P value = 0.01 shows evidence that there is a difference in how much patients who preferred stenting are willing to pay for surgery vs stenting.

Group of patient who preferred Stenting



Group of patients who preferred Surgery



17. Are any of your answers influenced by religious believes?

No - !00% of the patients in both groups

DISCUSSION

Studies such as this one come under the umbrella term of “behavioural medicine”, and as such are greatly different to clinical trials. They are qualitative by nature and are based on patients’ perception rather than actual medical data. It is common practice in such surveys to attempt to assess the effect on patients’ preference of comparative level of risk of the competing procedures and to see how the variation of risk level affects those (e.g. Oddone *et al*, 2002; Schwarze *et al*, 2006).

The question of hypothetical “out-of-pocket” costs is also frequently addressed. This also helps to assess the strength of interviewees’ preference for one procedure over the other (e.g. Pignone *et al*, 1999).

Having carried out a comprehensive review of such studies including those mentioned above I designed this pilot-study with a view to covering major areas of patients believes about the risks, side effects, type of anaesthesia and financial valuation of the carotid stenting and carotid endarterectomy.

The patients interviewed consisted of a mixture of: patients already participating in ICSS (the majority); patients undergoing neurological investigations at the outpatient stroke clinic; inpatients in the stroke unit.

This mixture of interviewee types should help to reduce any potential selection bias one way or another, which has been a concern of previous studies, (e.g. Warner et al, 2003). Nevertheless, in order to minimise interviewer influence I conducted all interviews in a uniform manner.

With regards to the actual answers obtained from the questionnaire, in the fundamental question of which treatment would be preferred there was a 2 to 1 proportion of patients preferring stenting to surgery.

Looking at the results subdivided by previous experience of either treatment, I can suggest that the majority of patients who preferred stenting had not had either treatment before, and only 2 of them had actually had stenting. However, of the 5 patients who preferred surgery, two each had previously undergone stenting and surgery. So, I would suggest that patients' preference in the group which preferred surgery was quite strongly influenced by procedures they had already experienced. In fact, one of the patients chose surgery for the sole reason that she had had a very unpleasant previous experience with stenting.

By contrast, there appeared to be no significant influence on patients' preference by previous experience of surgery of other types. It is also not possible to determine any outside influence on patients'

preferences due to the small number of friends and family who had undergone either treatment.

The question of anaesthesia appears to be quite important in patients' preference. All patients interviewed had experienced at least one type of anaesthesia. It is noticeable that the proportion, amongst patients who preferred stenting, in favour of local anaesthetic was exactly reflected in the proportion, amongst those preferring surgery, in favour of general anaesthetic. However, I must observe that the proportion (60:40) is not particularly decisive.

It may be that the anxiety felt towards surgical incisions by those preferring stenting partly corresponds with a liking for general anaesthesia amongst patients of an anxious nature.

I would suggest that the surprisingly large size of the minority of patients who preferred the type of anaesthesia not usually used for their preferred procedure should be a subject for further investigation.

Anxiety appeared to be a factor in the concerns of patients who preferred surgery with regards to local anaesthetic. A large minority did not like the idea of being able to watch the whole procedure, and the possibility of feeling pain was also significant in influencing their choice, whereas a similar majority amongst those preferring stenting were not concerned about these factors.

Regarding concerns about general anaesthesia, there was a minority in both groups with regards to all three factors (knife incision, scarring and past experience). The minority was smaller in all cases for those who preferred surgery. We can see that there is very little concern with scarring, even in the group preferring stenting. I would suggest that the age of the participants may well be a significant factor; I feel a younger age group may give different results.

Both sets of patients expressed some concern about side effects of stenting.

Predictably, some of those who preferred surgery are very worried about these (bruising or blood clot in the groin, temporary discomfort, neck or groin pain). Not surprisingly these results are mirrored in concerns about the side effects of surgery (scarring, blood clot, cranial and cervical nerve damage), with slightly more favourable results among the surgery group. I had expected less concern with side effects of surgery in the group which preferred that procedure. It appears that, in particular, the prospect of cranial nerve damage is of unexpectedly high concern to patients, and I believe that, as mentioned in the introduction, this particular side effect is of greater concern than previously thought.

Risk assessment was one of the clearest factors in patients' preference. Nobody regarded the unchosen option as not risky at all. One person who preferred surgery regarded both treatments as very risky, probably because he is highly anxious about any sort of intervention.

However, we can see that for the majority of patients who initially preferred stenting, the hypothetically raised risk of developing stroke after stenting did not cause them to change their preference to surgery.

Nobody claimed that religious beliefs affected their choice.

Finally, those who preferred stenting generally gave it a higher financial value than those who preferred surgery.

Limitations

In addition to the small number of patients, I am aware that this study has several other limitations.

Firstly, there is potential bias among patients who have already undergone one or other procedure as they are already participating in the ICSS.

Secondly, there were administrative delays in access to patients for regulatory and ethical reasons.

Thirdly, limited available time before project deadline.

Modifications

Among issues which I feel would need to be addressed in any future study are:

- to interview outpatients at a more suitable time. They were often unwilling to answer questions because of anxiety over imminent investigations and diagnosis.
- To interview a more varied selection of patients. There was too high a proportion of ICSS participants.
- To interview patients of a wider age group
- To modify certain questions; in particular to clarify the wording of the question regarding how much they would be prepared to pay, to improve the variety of possible concerns with the two methods of anaesthesia, and to offer a possibility of a hypothetical lower risk of stroke following stenting.

CONCLUSION

This study suggests that the following factors contribute significantly towards patients' preference between CAS and CEA:

- 1) Perception of comparative risk of the two procedures
- 2) Anxiety concerning general versus local anaesthesia
- 3) Concern about side effects.

There was a majority of patients in this pilot-study who preferred stenting over surgery, but the sample is too small to draw a statistically significant conclusion. A larger study is required in future.

REFERENCES

Ballotta Enzo, MD, Giuseppe Da Giau, MD, Laura Renon, MD, Surendra Narne, MD, Marina Saladine, MD, Elvira Abbruzzese, MD, Giorgio Meneghetti, MD; 1999; Cranial and cervical nerve injuries after carotid endarterectomy: A prospective study; *Surgery*; 125; 85-91.

Barnett Henry J.M. MD, D Wayne Taylor, MA, Michael Eliasziw, PhD, Allan J. Fox, MD, Gary G. Ferguson, MD, R. Brian Haynes, MD, Richard N. Rankin, MD, G. Patrick Glagett, MD, Vladimir Nachinski MD, David L. Sackett, MD, Kevin E. Thorpe, M. Math, Heather E. Meldrum; 1998; Benefit of carotid endarterectomy in patients with symptomatic, moderate or severe stenosis; volume 339; number 20.

Barrett K.M, Brott T.G; 2006; Carotidartery stenting versus carotid endarterectomy: current status; 24(4); 681-95.

Brooks W.H, MD, Rick R. Mc Clure, MD, FACC, Michael R. Jones, FACC, Timothy C. Coleman, MD, Linda Breathitt, RN; 2001; Carotid Angioplasty and Stenting Versus Carotid Endarterectomy: Randomized Trial in a Community Hospital; *Journal the American College of Cardiology*; vol. 38; No. 6.

Brown.M.M *et al*; 2001; Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Artery

Transluminal Angioplasty Study (CAVATAS): a randomisae trial;
Lancet; 357; 1729-37.

Internetal Carotid Stenting Study (ICSS) Protocol; 2004.

Beresford N, Seymour L, Vincent C, Maot N; 2001; Risks of elective
cardiac surgery: what do patients want to know?; Heart; 86; 626-631.

Cao Piergiorgio, MD, FRCS, Paola De Rango, MD, Fabio Verzini,
MD, Agostino Maselli, MD, Lucia Norgiliony, MD, Giuseppe
Giordano, MD; 2006; Outcome of carotid stenting versus
Endarterectomy. A case-control study; Stroke; 37. 1221.

De Borst GJ, Hellings We, Ackerstaff RG, Moll FL, Antonius
Carotid Endarterectomy, Angioplasty and Stenting Study Group;
2006; J Cardiovascular Surgery; 47(1); 49-54.

Donaldson Cam, Shackley Phil; 2003; Willingness to pay for health
care; Advances in Health Economics.

European carotid Surgery Trialists' Collaborative Group; 1998;
Randomised trial of endarterectomy for recently symptomatic carotid
stenosis: final results of the MRC European Carotid Surgery Trial
(ECST); Lancet; volume 351 (9113); 1379-1387.

Jones HR. Jr, MD; 2005; Netter's Neurology.

Kastrup A. MD, Joerg b. Schulz MD, Sabine Raygrotzki MD, Klaus
Groschel Md, Ulrike Erneman MD; 2004; Comparison of angioplasty
and stenting with cerebral protection versus endarterectomy for

treatment of internal carotid artery stenosis in elderly patients;

Journal of vascular surgery; vol 4 (5); 945-951.

Kilaru s, Korn p, Kasirajan K, Lee TY, Beavers TY, Lyon RT, Bush HL, Kent KC; 2003; Is carotid angioplasty and stenting more cost effective than carotid endarterectomy?; J Vasc Surgery; 37 (2); 331-9.

Kilary s, Thomas Lee, Harry L. Bush Jr, K Craig Kent; 2002; Endarterectomy vs stent angioplasty: what is the optimal treatment of carotid stenosis?; Cardiovascular surgery; vol.10; No.4; 366-371.

Naylor AR; 2007; Where Next after SPACE and EVA-3S: “The good, the Bad and the Ugly!”; European Journal of Vascular and Endovascular Surgery; vol.33 (1); 44-47.

Naylor AR, 2006; SPACE: not the final frontier; Lancet; 368 (9543); 1239-47.

Mas Jean-Louis, *MD et al*; 2006; Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis; New England Journal of Medicine; 355; 1660-71.

Oddone E.Z, MD, MHSc, Ronnie D Horner, PhD, Dean
C.C.Johnston, MD, MHSc, Karen Stechuchak, MS, Lauren McIntyre, PhD, Aileen Ward, RN, MSN, Linda G. Alley, RN, PhD, Jeff Whittle, MD, Laura Kroupa, MD, John Taylor, MD; 2002; Carotid

endarterectomy and Race. Do clinical Indications and Patient preferences account for differences?; Stroke; 33; 29-36.

Pignone Michael, MD, MPH, Dawn Bucholtz, MA, MPH, Russel Harris, MD, MPH; 1999; Patient Preferences for Colon Cancer screening; J Gen Intern Med; 14; 432-437.

Schwarze ML, Sayla MA, Alexander GC; 2006; Exploring patients preferences for Infrainguinal Bypass Operation; Journal of the American College of Surgeons; vol.202(3) 445-452.

Skillman JJ, Kent KC, Anninos E; 1994; Do neck incisions influence nerve deficits after carotid endarterectomy?; 129(7); 784-52.

Senple PF, Ralph L. Sacco; 1999; An Atlas of Stroke.

SPACE collaborative Group; 2006; 30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial; Lancet; vol.368 (9534); 1239-1247.

Taylor S, Francisco Alcocer, William D.Jordan, Jr; 2003; Controversies in Carotid Stenting; Vascular and Endovasc Surgery; 37(2).

Timler D, Stelagowski M, Kasielska A, Bogusiak K, Tazbir.J;2007; Analysis of surgical treatment of patients with carotid artery stenosis endarterectomy versus stenting; Acta Chir Belg.; 107 (2); 146-50.

Warren JA, Jordan WD, Heudebert GR; Whitley D; Wirthlin DJ,
2003; Determining patient preference for treatment of axtracranial
carotid artery stenosis: carotid angioplasty and stenting versus carotid
endarterectomy; *Annals of vascular surgery*; 17; 15-21.

Wolfe, 2000; *Stroke British Medical Bulletin*.

Appendix

Questionnaire

1. What treatment would you prefer: stenting or surgery?
2. Could you score each treatment according to your preference on a linear scale of 1 to 10 where:

1- I would not have treatment under any circumstances.

10 - I am extremely keen to have this treatment

My feelings about stenting

My feelings about surgery

3. Have you had any of these treatments before?

Answer: Yes, surgery.
Yes, stenting.
Yes, both.
No, neither

4. Have you had stenting elsewhere in a body?

Answer: Yes
No

5. Have you had major surgery elsewhere in a body?

Answer: Yes
No

6. Has any member of your family or close friends had one of these treatments?

Answer: Yes
No

7. Have you experienced either general or local anaesthesia?

Answer: Yes, local.
Yes, general.
Yes, both.
No, neither.

8. Given a necessity to have anaesthesia, which of these two would you prefer?

Answer: Local

General

9. If you had local anaesthesia would you be concerned about the following?

- | | | |
|---|-----|----|
| a. being able to watch the whole procedure. | Yes | No |
| b. being able to feel pain during the surgery | Yes | No |
| c. past experience with local anaesthesia. | Yes | No |

10. If you had general anaesthesia would you be worried about the following?

- | | | |
|---|-----|----|
| a. knife incision in your neck | Yes | No |
| b. appearance (scar after surgery) | Yes | No |
| c. past experience with general anaesthesia | Yes | No |

11. Are you worried about the side effects of the treatment?

For stenting:

bruising or blood clot in the groin, temporary discomfort or pain in the neck or groin

- very worried
- somewhat worried
- hardly worried
- not worried at all

For surgery:

permanent scar on the neck, blood clot may form on the of the incision, numbness and weakness of the face, problems with your speech and swallowing

- very worried
- somewhat worried
- hardly worried
- not worried at all

12. Do you consider carotid stenting:

- very risky
- somewhat risky
- hardly risky
- not risky at all

13. Do you consider carotid surgery:

- very risky
- somewhat risky
- hardly risky
- not risky at all

14. Now we would like to know what level of risk of stroke you would be prepared to take when considering the treatment.

Please consider the following risks of stroke at the time of the treatment and think if you would still prefer one treatment or if you would change your mind. Assume that both are equally good at preventing stroke

Tables for risk of having a stroke caused by the treatment:

Treatment	Number of patients having a stroke for every 100 patients treated
stenting	10 in 100
surgery	5 in 100

What treatment would you prefer? stenting

surgery

Treatment	Number of patients having a stroke for every 100 patients treated
stenting	9 in 100
surgery	5 in 100

What treatment would you prefer? stenting

Surgery

17. Were any of your answers influenced by religious beliefs?

Yes

No

Patient information sheet

You are invited to participate in a research project we are running to determine the factors contributing towards patient's preference between two competing treatments: carotid stenting vs carotid surgery.

Why have you been selected? You are having tests to find out the cause of your symptoms. This includes the tests to see if you have narrowing of the carotid arteries. If you were found to have carotid artery narrowing you might need treatment to remove the narrowing. It is unlikely that you will have carotid narrowing but we would like to find out your views if treatment has been required.

Narrowing of one of the carotid arteries in the neck, which supply blood to the brain, is an important cause of stroke. It is therefore important to remove this narrowing to prevent stroke.

The traditional method of treatment is a surgical operation (endarterectomy), often performed under general anaesthetic, in which a diseased part of artery is cut out through an incision in the neck. Patients have to stay in hospital for several days after surgery.

In the other treatment, which is known as a carotid stenting, a small tube made of mesh, called a stent, is placed inside the narrowed artery in the neck. The stent is placed into the artery through a small tube (catheter) inserted in the groin under local anaesthetic. Injections of dye will be made through the catheter to take X-ray pictures of the narrowing. This called angiography. Once in position across the narrowing the stent is opened out where it acts like a spring to keep the artery open. Stenting avoids the discomforts of surgery and risks of general anaesthesia. If patients are well after the stenting procedure they will be able to go home.

What are the main risks of treatment?

Both surgical endarterectomy and stenting carry a risk of causing a stroke at the time of the treatment. There is a small risk of about one in a hundred that angiography will cause a stroke. However, the risks of the strokes resulting from surgical or stenting treatment are believed to be less than leaving the carotid narrowing untreated.

What are the other main risks of surgery? Surgery also has a risk of causing heart attack. About one in ten patients has temporary tongue or facial weakness. A large blood clot (haematoma) may form at the site of incision, which may require evacuation. Surgery results in a permanent scar in the neck.

What are the other main risks of stenting? Angiography and stenting may also result in bruising or haematoma at the site of injection (usually the groin) and can cause temporary discomfort or pain in the neck. There is a small risk of allergic reactions to the dye.

